COVID-19 Schools Infection Survey

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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*"

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1.0 AMENDMENT HISTORY

Amendment No.	Protocol Version	Date issued	Author(s) of changes	*Details of Changes made*
1	*1.2*	*18/12/2020*	*Patrick Nguipdop Djomo*	*Recruitment within secondary schools extended from 2-year groups to additional year groups* *Enrolment of new participants period extended beyond round 1 to throughout the study period until last round of testing in July 2021*
2	*1.3*	*08/02/2021*	*Patrick Nguipdop Djomo*	*Details of compensation package offer for schools to support study activities (section 6.1)*
3	*1.4*	*14/05/2021*	*Sian-Elin Wyatt*	*End of study questionnaire issued to participants following the final virus test round.*
4	*2.1*	*01/10/2021*	*Shamez Ladhani*	*Major amendment for SIS study to continue with redesign into 2021/22 academic year (SIS-2)*
5	*2.2*	*13/01/2022* *27/01/2022*	*Gillian McKay/ Peter Jones*	*Inclusion of a nested qualitative study with 10 Head Teachers (or designated school staff members) to the SIS2 protocol* *A list of data sets for linkage by ONS for clarity*

2.0 BACKGROUND AND RATIONALE

The Schools Infection Survey was originally commissioned for the academic year 2020/21. We have retained the original content from previous versions of the protocol and referenced headings accordingly as 'Year 1' throughout the document. Additional sections outlining changes in direction for the study over the next academic year are headed as 'Year 2'.

2.1 Year 1

In December 2019, a new disease, coronavirus disease 2019 (COVID-19), caused by a novel virus "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), was identified in the Wuhan region of China and is currently causing a global pandemic. COVID-19 is primarily a respiratory illness that can be severe and fatal, especially in older adults. Severe COVID-19 is associated with pneumonia and damage to vital organs including lung, heart, liver, and kidney.

In England, the emergence of COVID-19 led to national lockdown with closure of all educational settings in late March 2020. Children and young people of key workers, however, continued to attend school throughout the outbreak. Cases in England increased rapidly until mid-April before declining gradually.

From 01 June 2020, as part of easing of the lockdown, children in reception, year 1 and year 6 were allowed to return and, from 15 June, years 10 and 12 attended schools, but with social distancing and infection control measures in place, including significantly small class sizes. From September, all students have started attending school.

Schools have received government advice about measures to reduce transmission risk. These include requiring those who have 1 or more symptoms consistent with COVID-19 to stay home, hand and respiratory hygiene practices, enhanced cleaning arrangements, suggested use of face coverings in communal areas, grouping children together and avoiding contact between groups, arranging classrooms with forward facing desks, and staff maintaining distance from each other and students. School leaders make decisions regarding the introduction of protective measures based on risk assessments and the local needs of schools and communities. It is likely that which measures are being attempted in which schools, the extent to which measures are being implemented and the challenges schools have faced in doing so will vary. There are widespread concerns about the impact of the pandemic, lockdown and implementing school preventive measures on the mental wellbeing of staff and students, and how, in turn, this may influence the success of implementation.

In June 2020, PHE initiated COVID-19 surveillance in preschools and primary schools. A team involving Public Health England (PHE), the Office for National Statistics (ONS) and the London School of Hygiene and Tropical Medicine (LSHTM) proposes to extend this surveillance nationally to a larger sample of both primary and secondary schools across England for the 2020/21 school year.

The aim is to assess the role of schools in SARS-CoV-2 infection and transmission within school settings. Repeated surveys will be carried out to collect risk factor information together with virus and antibody samples in a cohort of children and staff. Antibody conversion and viral prevalence at points in the academic year will be key outcome measures.

To complement sample testing and assess transmission we will also:

- track attendance patterns, including partial and full school closures over time
- assess what control measures schools are implementing and how they are being implemented
- In some schools, where there is evidence on potential transmission, undertake detailed outbreak investigations

2.2 Year 2

The first Schools Infection Survey (SIS-1) 2020/21 provided crucial evidence about the prevalence of asymptomatic infection and transmission amongst pupils and staff in primary and secondary schools in England.

Following recommendations from the Scientific Advisory Group for COVID-19 surveillance in schools and business case approval from DHSC, the Schools Infection Survey has been recommissioned for the next academic year (SIS-2) 2021/22. SIS-2 will look beyond questions about COVID-19 transmission in schools and have a renewed focus on school recovery and resilience as the country prepares for potential further waves of infection in Autumn 2021.

Central to (SIS-2) is construction of a national level data asset that provides a comprehensive view of the school population in England. Record level data from COVID-19 testing programmes (e.g. schools rapid testing, Test and Trace) will be linked to a number of DHSC and DfE sources, including clinical data, educational attainment, and school attendance. While the data asset proposed will have good coverage of the school population in England, the existing data streams currently available will not provide the level of detailed insights needed to understand the extent of schools' recovery and the broader health and wellbeing impacts of the pandemic on children.

SIS-2 will therefore continue with a sample of schools from which detailed information can be collected, to ensure information needs are fully met to address primary research objectives in schools. A series of questionnaires for secondary pupils and headteachers will fill in the gaps in critical data that is not widely collected in key topic areas, including long COVID in children, their mental health, and vaccine sentiment. A small nested qualitative study will conduct 10 in-depth-interviews with school Head Teachers (5 primary and 5 secondary) to delve further into responses from the Head Teacher questionnaire.

SIS-2 will also proceed with biological sampling of antibodies in a sample of 180 schools in England using the PHE oral fluids test. This data will be collected from children only, continuing in part with the existing cohort of SIS-1 pupils (approx. 12,000) plus additional sample (approx. 8,000 pupils) to ensure that resulting estimates are nationally and regionally generalisable.

3.0 AIMS AND OBJECTIVES

3.1 Primary aims

3.1.1 Year 1

In a sample of primary and secondary schools in England

1. To estimate the incidence of SARS-CoV-2 seroconversion (antibody negative to antibody positive) among children and staff in a sample of primary and secondary schools, measured at termly intervals during the school year.
2. To measure the prevalence of current SARS-CoV-2 infection among children and staff in these primary and secondary schools, measured at half-termly intervals during the school year.
3. To monitor student and staff attendance rates in a sample of primary and secondary schools, and the proportion of and reasons for school full or partial closure.
4. To assess the feasibility, acceptability and staff, student and parent experience of school implementation of SARS-CoV-2 control measures, and factors affecting this.

To conduct detailed investigations of selected outbreaks occurring in schools, to determine the risk of transmission within and between classes and schools, and between students, staff and other household members.

3.1.2 Year 2

In a sample of primary and secondary schools in England

1. What is the coverage and feasibility of implementing prevention and control measures in schools and how do they change over the school year?
2. What is the Impact of COVID-19 on student well-being: mental health, “long COVID”, school attendance, educational engagement, attainment and employment prospects?
3. What is the rate and pattern of COVID-19 infection and immunity in pupils and staff at start and end of term and how do they relate to staff vaccination, new variants of concern and other control measures (community or school)?
4. What are the patterns of respiratory virus infections causing outbreaks and absences among students and staff and how do they vary over the year*?*
5. What is the impact of changes in control measures including routine and new vaccination programmes on infections causing school outbreaks or absences?

3.2 Secondary aims

3.2.1 Year 1

1. To pilot the detection and monitoring of SARS-CoV-2 in school wastewater.
2. To investigate individual, school and community-level risk factors for higher prevalence of SARS-CoV-2 infection, antibodies and antibody seroconversion among school students and staff.
3. To investigate the patterns of social contact between students and staff while in school.

3.2.2 Year 2

1. To address new research questions as these are identified by the study sponsors and steering group during the year.

4.0 STUDY DESIGN

4.1 Overview of the study design

4.1.1 Year 1:

The aims of this study will be achieved through repeat surveys in a sample of schools, during which cohorts of pupils and parents will be invited to complete questionnaires, and to participate in testing for SARS-CoV-2 infection and antibodies. Tests for students will involve a nose swab for current SARS-CoV-2 infection (Please note: this is not the nasopharyngeal swab that takes a sample from deep into the back of the nose), and an oral fluid (saliva) sample for antibodies against the virus. Tests for staff will involve a nose swab for current SARS-CoV-2 infection and a finger prick blood test for antibodies against the virus. Incidence of antibody conversion will be assessed by determining the proportion of those negative at baseline testing who are found to be antibody positive in subsequent rounds. Other epidemiological parameters will be calculated from the data. A sample of outbreaks in schools that occur among the sample of schools will be investigated in detail.

The study will also include a survey and semi-structured interviews with school staff, students and the parents/carers of students. Attendance information will be collated through existing records, which will provide detailed information about schools and their implementation of control measures. Further sub-studies are planned, including piloting the use of waste water surveillance.

4.1.2 Year 2:

The aims of this study will continue to be achieved through repeat surveys in a sample of schools, during which cohorts of secondary pupils and headteachers will be invited to complete questionnaires, and pupils to participate in testing for SARS-CoV-2 antibodies. Tests for pupils will involve an oral fluids (lollipop) samples for antibodies against the virus. Incidence of antibody conversion will be assessed by determining the proportion of those negative at baseline testing (including those baseline tests that were collected from the sub-cohort of participants taking part in SIS-1) who are found to be antibody positive in subsequent rounds. Other epidemiological parameters will be calculated from the data. The questionnaire and antibody data collected from SIS-2 participants will be linked to a range of health and education datasets including, school census and school attendance information, vaccine data, Test and Trace (inc. rapid testing in schools), hospital episodes and GP records. ONS will assume responsibility for liaising with relevant government departments to acquire access to (but not exclusively restricted to) the following datasets for this purpose:

- English School Census
- School Workforce Census
- National Pupil Database (NPD)
- National Immunisation Management Service (NIMS)
- Personal Demographic Service (PDS)
- Hospital Episode Statistics (HES)
- General Practice Extraction Service (GPES)
- Medicines dispensed in Primary Care NHS Business Services Authority (NHSBSA)
- Mental Health Services Data Set (MHSDS)
- Emergency Care Data Set (ECDS)
- NHS Test and Trace data
- 2021 Census

Headteacher questionnaires will continue to collect some information about control measures in schools, but will have a renewed focus on air flow and ventilation of school premises and the provision of mental health services for children. The Head Teacher qualitative interviews will build on the questionnaires by asking in-depth questions about the challenges to control measures, mitigation innovations in schools, mental health provision for pupils/staff and other areas of interest identified from the questionnaire responses.

4.2 Target population: Inclusion and Exclusion criteria

4.2.1 Year 1:

Schools:

Inclusion Criteria

- Primary and secondary schools in England.

Exclusion criteria

- Special schools, pupil referral units or further education colleges. We will also not recruit schools where other school-based COVID-19 studies are already being conducted.

Participants:

Inclusion criteria

- We will offer enrolment to students and staff attending school in person during the 2020/2021 academic year.

Exclusion criteria

- Where possible, students from years 11 will not be offered enrolment because they will be taking public examinations at the end of the academic year.
- We will not offer enrolment to secondary school students when judged by school staff as being not competent to provide informed consent.

4.2.2 Year 2:

Schools:

Inclusion Criteria

- Primary and secondary schools in England.

Exclusion criteria

- Special schools, pupil referral units, independent schools or further education colleges. We will also not recruit schools where other school-based COVID-19 studies are already being conducted.

Participants:

Inclusion criteria

- We will offer enrolment to parents of pupils in reception to year 11 and pupils in years 12 and 13 attending school in person during the 2021/2022 academic year to take part in Antibody testing of pupils and online surveys (parents to complete for primary pupils, pupils to complete for secondary age).
- We will offer participation in the in-depth interviews to 10 Head Teachers (or a designated staff member) chosen from already enrolled SIS-2 schools, with the intention of recruiting 5 from primary schools and 5 from secondary, across a variety of geographic regions.

Exclusion criteria

- We will not offer enrolment to secondary school pupils when judged by school staff as being not competent to provide informed consent.
- We will not offer participation in the Head Teacher qualitative interview to schools that already had their leadership interviewed in SIS-1, as the questions are similar and we seek to speak to new schools to hear their experience.

4.3 Sample

4.3.1 Year 1:

We will take a stratified random sample of schools, with separate samples for primary and secondary schools. We will aim to oversample schools in parts of the country where the risk of SARS-CoV-2 infection is higher.

Sampling frame and sampling approach

The first level of sampling is local authority area. We grouped local authorities (LAs) in England into two groups based on COVID-19 prevalence level.

Group 1 LAs were those in the top 20% when ranked by rate of confirmed cases of Sars-CoV-2 infection /100,000 population from Pillar 2 testing in the week 2nd to 8th September 2020. We then randomly sampled 10 LAs from Group A (66% of the sampled LAs)

Group 2 were those in the lower 80% when ranked by rate of confirmed cases of Sars-CoV-2 infection /100,000 population from Pillar 2 testing in the week 2nd to 8th September 2020. We then sampled 5 LAs from Group B (33% of the sampled LAs)

We analysed the association between COVID prevalence and Index of Multiple Deprivation (IMD) and found an association such that Group 1 LAs had higher IMD than Group 2 LAs. The analysis of data up till 13 May 2020 by PHE has shown that those living in deprived areas had a higher risk of COVID-19 than those in less deprived areas and we wished to ensure good representation of higher IMD areas in the sample (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf).

The second level of sampling is schools. The sampling frame was the list of schools and the number of pupils enrolled available at the "Get *Information About Schools*" website (https://get-information-schools.service.gov.uk/), which contains a comprehensive list of all schools in England. The aim was to sample schools in order to end up with a sample of schools with approximately 70% (70 secondary and 35 primary) schools in high risk area and 30 % (30 secondary and 15 primary) in lower risk areas.

The 15 LAs that were randomly sampled have considerable variability in the number of schools listed on the frame. Allowing each school to have an equal selection probability would result in larger LAs having a higher proportion of sample allocation. To distribute the sample more evenly across the LAs we used appropriate weighting to randomly sample schools with probability inverse to the number of schools in each LA. This means that some of the smaller LAs have a disproportionately higher proportion of schools selected. This has the advantage of spreading resources more evenly across the LAs, and results in a similar number of schools being sampled in each LA.

We analysed distributions for the proportion of children attending each school that were entitled to free school meals. Schools in Group 1 of our sample (those in higher risk areas) had a higher school meal entitlement than schools in Group 2 (lower risk). Using this as an indicator of relative deprivation between the two groups, we were satisfied that the schools selected across the two sample strata were distinct in terms of deprivation, which is known to be a predictor of SARS-COV2 prevalence.

The third level of sampling is individual level. Within all selected schools:

In primary schools, where the average enrolment is 280 pupils, we will offer enrolment to

- all eligible students
- and all staff.

In secondary schools, where the average enrolment is 990 pupils, we will only offer enrolment to

- For logistic reasons, we initially planned to restrict enrolment to two consecutive year groups in each secondary school (approximately 250 students). However, in view of the lower-than-expected response rate, we have decided to extend enrolment to additional year groups in the schools participating to the study.
- and all staff.

In a simulation of the sampling exercise, this resulted in an approximate total eligible population of:

- 35-36,000 Secondary school students (in selected year groups)
- 10-11,00 Secondary school staff
- 13-14,000 Primary school students
- 1-2,000 Primary school staff

Sample size:

The overall sample size was constrained by testing capacity for both antibody and virus testing. Between each round of testing throughout the school year, we estimate that

approximately 40,000 antibody and virus tests can be taken from school pupils and staff and processed in labs with sufficient timeliness to notify participants of results and analyse data for reporting purposes.

We determined that the optimum allocation of sample was to prioritise secondary schools, since evidence so far suggests SARS-CoV-2 transmission appears to be higher amongst older children. To reduce clustering effects and enable more secondary schools to be enrolled we initially selected two year-groups from each secondary school. This enabled us to include a total of 100 secondary schools. With the remaining sample allocation, we selected 50 primary schools for whole school testing. The scale of whole school testing in the average sized primary school is roughly equivalent to that of testing two year-groups in the average sized secondary school. In view of the lower-than-expected response rate in secondary schools after the initial round of testing, we have decided it is feasible to extend enrolment to additional year groups.

We further assumed a response and follow up rate of 60% among students (~170 students recruited and followed up per primary school and ~150 per secondary school) and up to 90% among staff. To ensure we achieve participation from at least 150 schools, we will oversample and invite a larger number of schools to take part in the study (between 200-250 schools). Should we have a very high response rate, we will select 150 schools optimally to ensure the desirable split between strata 1 and 2 (high risk and low risk areas), and an even distribution across the 15 local authorities. This selection will involve random selection from strata to minimise bias while ensuring we include the relevant categories of schools.

Precision of estimates and assumptions

Assuming that about 10% of pupils and staff have a positive antibody test at enrolment and an average weekly incidence of 1 infection per 1000, with limited antibody reversion, and assuming a design effect (DEFF) of 2.3 for antibody testing to account for clustering, we can estimate cumulative incidence of seroconversion rate and its precision. In the autumn term (Sep-Dec 2020), samples will be collected after the half-term and at the end of term (4-6 week interval). After the autumn term the period between antibody tests will be ~12 weeks. Based on the sample sizes above, the table below shows the cumulative incidence of seroconversion over different follow-up periods with the statistical precision below for each group at 95% confidence level:

Estimates of seroconversion rate with 95% confidence intervals at different follow-up periods

	Approx. number of individuals included*	4 weeks between follow up	8 weeks between follow up	12 weeks between follow up
Secondary staff	10,620	0.4% - 95% CI (0.2%-0.6%)	0.8% - 95% CI (0.5%-1.1%)	1.2% - 95% CI (0.9%-1.5%)
Secondary students	20,400	0.4% - 95% CI (0.3%-0.5%)	0.8% - 95% CI (0.6%-1%)	1.2% - 95% CI (1%-1.4%)
Primary staff	1,440	0.4% - 95% CI (0.0%-0.9%)	0.8% - 95% CI (0.1%-1.5%)	1.2% - 95% CI (0.3%-2.1%)

Primary students	8,460	0.4% - 95% CI (0.2%-0.6%)	0.8% - 95% CI (0.5%-1.1%)	1.2% - 95% CI (0.8%-1.6%)

**assumes 60% of eligible students and 90% of eligible staff contribute to analysis, with 10% antibody prevalence at enrolment, and a design effect of 2.3*

There is little information currently available to calculate the increased variance as a consequence of sampling entire schools or school year-groups as opposed to simple random sampling of pupils in the population. The DEFF of 2.3 used here is based on the assumption of an average prevalence of 10% antibody at enrolment, and a between-school standard deviation of 2.5% (i.e. 95% of schools are between 5 and 15%), with 150 to 200 pupils enrolled per school. The projected sample size gives good precision for estimates of antibody seroconversion among secondary school staff and students, and primary students, with less precision among primary staff.

4.3.2 Year 2:

We will rebalance the sample of schools this year, to ensure that we can produce robust estimates of antibody prevalence in children at regional and national level.

We've made three assumptions in our sample size calculations:

- A 95% confidence interval of +/- 5% is an acceptable level of precision for regional estimates
- COVID-19 antibody prevalence in children could reach (and exceed) 50% of school pupil population over the next academic year
- A design effect of 2.3 to account for clustering in the sample design

On this basis we require 13 primary schools and 7 secondary schools in each region. The table below shows the regional breakdown of existing schools we will retain in sample, and the number of school additions to rebalance the sample in each region. Overall, we would aim to retain 57 schools, and recruit a further 123, making a total of 180 schools in this year's study.

Region	Primary		Secondary	
	Current sample	Additional required	Current sample	Additional required
East Midlands	2	11	1	6
East of England	3	10	3	4
London	0	13	2	5
North East	13	0	7	0
North West	7	6	7	0
South East	3	10	3	4
South West	3	10	3	4
Yorkshire and The Humber		13	-	7
West Midlands		13	-	7
Grand Total	**31**	**86**	**26**	**37**

Note: A sample of this size is only required to produce estimates of precision when anti-body prevalence in the school pupil population is close to 50%. We have simulated other prevalence scenarios (both higher and lower), where smaller sample sizes will enable us to achieve the

equivalent levels of precision. If we sample this many schools we would expect to achieve approximately 20,000 participants / Antibody tests

Sampling frame and sampling approach

We will use the same sources used to construct the sample frame of schools in year 1, but with updated information about schools for the 2021/22 academic year.

The first level of sampling is local authority area (LA). Within each region, we will sort the LAs according to an urban/rural indicator to ensure a sample which is distributed at a regional level. We will select the LAs with probability proportional to size, so we are more likely to sample LAs which have more schools, as this has beneficial effects on the variability of the weights. We will select 5 local authorities within a region.

The second level of sampling is at school level. We will stratify schools by percentage of pupils eligible for free school meals (% FSM). This will ensure we are sampling schools which have different characteristics so therefore will be more representative of the region as a whole. We will select a total of 7 secondary and 13 primary schools within each region. All pupils within a selected school will be eligible

The clustering is necessary to enable to sample to be operationally efficient and to maximise response. We will account for the design effect when weighting our estimates.

4.4 Procedures

4.4.1. Core participation procedures

4.4.1.1 Year 1:

- The sampling frame will be prepared, the schools sample identified and schools will be approached for their participation. The purpose of the study and what participation involves will be explained to head teachers who, with their chairs of governors, will be asked to agree to their school participating in the study. LAs and DPHs and, where relevant, the management of academy chains will be informed about the study and will encourage schools to participate.
- Schools that agree to participate will be asked register and complete a short questionnaire.
- Headteachers from participating secondary schools will be approached to discuss the extension of enrolment to additional year groups
- Informed consent will be sought from staff, from parents of students aged <16 years and from students aged 16 years or over. Multiple children from one family can participate, but separate consent will be sought for each child.
- Head teachers of participating schools will provide information about the survey to staff, parents of students aged <16 years and from students aged 16 years or over. An electronic link will provide information about the study, an online consent form and a short online questionnaire. For primary school students and secondary school students younger than 16 years we will ask parents/guardians to involve their children in the decision process by explaining why this surveillance is being undertaken and how their children can help by taking part.
- Age-appropriate information will be provided for the students.

- A study team will visit the school to collect biological samples for testing (see details below)
- On the day, samples will be taken from participants who have given consent and completed the online questionnaire. Those not at school on the day will be sent instructions and testing kits to their homes for completion and return.
- Additional online questionnaires will be sent to participants during the surveillance period.
- For subsequent rounds of testing, participants will receive advanced notification of the sample collection day, with a short follow-up questionnaire.
- Following the 6th round of virus testing all participants will receive an online end of study questionnaire to complete.
- Online surveys and interviews will be conducted with four groups: (1) head teachers or a substitute member of the school senior leadership team (SLT), (2) school staff, (3) parents of students enrolled at participating schools and (4) secondary school students.
- A subset of schools will be selected, and wastewater samples will be collected at regular intervals for the detection of SARS-CoV-2

4.4.1.2 Year 2:

- The sampling frame will be prepared, the schools sample identified and schools will be approached for their participation. We intend that approximately 60 of the schools will be continuing their participation from last year. A further 120 schools will be approached and invited to take part as new participant schools in the study. The purpose of the study and what participation involves will be explained to head teachers who, with their chairs of governors, will be asked to agree to their school participating in the study. LAs and DPHs and, where relevant, the management of academy chains will be informed about the study and will encourage schools to participate.
- Schools that agree to participate will be asked to register and complete a short questionnaire.
- Informed consent will be sought from parents of pupils up to and including year 11 and from pupils aged 16 years or over studying in sixth form. Multiple children from one family can participate, but separate consent will be sought for each child.
- Headteachers of participating schools will provide information about the survey to parents of pupils up to and including year 11 and to pupils in sixth form aged 16 years or over. An electronic link will provide information about the study, an online consent form and a short online questionnaire. For primary school pupils and secondary school pupils up to and including year 11 we will ask parents/guardians to involve their children in the decision process by explaining why this surveillance is being undertaken and how their children can help by taking part.
- Age-appropriate information will be provided for the pupils.
- A study team will visit the school to collect biological samples for testing (see details below)
- On the day, samples will be taken from participants who have given consent and completed the online questionnaire. We do not propose to send home test kits out for those children absent, as we anticipate the number of isolating pupils to be notably lower this year.
- Additional online questionnaires will be sent to participants during the surveillance period.
- For subsequent rounds of testing, participants will receive advanced notification of the

sample collection day.
- Online surveys and interviews will be conducted with three groups: (1) head teachers or a substitute member of the school senior leadership team (SLT), (2) parents of enrolled pupils at participating schools up to and including year 11, and (3) secondary school pupils.
- In-depth interviews will be conducted through an online platform (Zoom or similar) with Head Teachers following an informed consent process.

4.4.2 Samples collection

4.4.2.1 Year 1:

- A field investigation team will visit the schools on pre-agreed days to coordinate the sampling.
- Where possible, testing will take place on a single day; additional days may be agreed with the schools where necessary. Tests will take place in school or a nearby setting agreed with the school.
- We will ask the head teacher to notify participants about the date of biological testing in advance. We will also inform the participants by text/emails as required.
- Infection control measures will be implemented during the collection of samples
- The following samples will be taken:
    - nose swabs from all consenting participants (students and staff).
    - oral fluid samples from students
    - finger-prick blood sample from staff;
- The study will seek to achieve high levels of follow-up for enrolled participants. Where necessary, this will include making special arrangements to contact students or staff who are not in school or college by post or on follow-up study visit days.

- Samples will be linked to questionnaires through a unique ID and barcode.
- In participating schools, the opportunity to enrol to the study will remain open to all eligible pupils and staff throughout the study period, up until the last visit in July 2021.

4.4.2.2 Year 2:

- A field investigation team will visit the schools on pre-agreed days to coordinate the sampling.
- Where possible, testing will take place on a single day; additional days may be agreed with the schools where necessary. Tests will take place in school or a nearby setting agreed with the school.
- We will ask the headteacher to notify participants about the date of biological testing in advance. We will also inform the participants by text/emails as required, and the results of antibody test will be shared with participants as soon as they are available.
- Infection control measures will be implemented during the collection of samples
- The following samples will be taken:
    - oral fluid samples from school pupils

- The study will seek to achieve high levels of follow-up for enrolled participants. Where necessary, this will include making special arrangements to contact pupils who are not in school or college by post or on follow-up study visit days.
- Samples will be linked to questionnaires through a unique ID and barcode.
- In participating schools, the opportunity to enrol to the study will remain open to all eligible pupils throughout the study period, up until the last visit in March 2022.

4.4.3 Processing and testing of biological samples

4.4.3.1 Year 1:

- Nose swabs will be appropriately labelled and sent to a national testing centre for RT-PCR. Every attempt will be made to report any positive swab results to individuals and schools as quickly as possible, ideally within 48 hours so that the individual and household members can self-isolate and the school can take appropriate actions to protect staff and students who may have come into contact with the positive participant, as per national guidance.
- Positive swab (PCR) samples will also be forwarded to PHE for genomic sequencing.
- Staff will have a finger prick for measurement of antibodies at the same time as the swab.
- The oral fluid samples will be couriered to PHE Colindale where they will be batch tested for SARS-CoV-2 antibodies. Because antibody testing using oral fluids is a laborious process, the results of the antibody tests may take several weeks before they become available because of the large number of surveillance programmes being undertaken by PHE.
- Positive test results will also be reported to the test, trace and isolate (TTI) programme and the local health protection team (in case of an outbreak)
- Additional investigations including swabs and antibody testing may be performed following agreement with the positive participant and household members
- Additional investigations in the wider educational settings may also be undertaken in collaboration with the school and the local health protection team, especially if more than one case is confirmed in a school
- Any remaining samples at the end of the survey will be stored for future tests that might help us better understand viral infections and immunity

4.4.3.2 Year 2:

- The oral fluid samples will be couriered to PHE Colindale, or other agreed labs identified by DHSC to have capacity and the necessary accreditation to support processing of samples. The samples will be batch tested for SARS-CoV-2 antibodies. Because antibody testing using oral fluids is a laborious process, the results of the antibody tests may take several weeks (up to 4 months) before they become available because of the large number of surveillance programmes being undertaken by PHE.
- Any remaining samples at the end of the survey will be stored for future tests that might help us better understand viral immunity.

4.4.4 Outbreak investigation

4.4.4.1 Year 1:

As part of its commitment to public health management of COVID-19 in institutional settings, PHE will coordinate risk assessments and more extensive investigations in selected outbreaks (two or more linked cases in a single school within two weeks), which will include wider testing among staff, students and their households as identified by the risk assessment.

4.4.4.1 Year 2:

For the second year of study (2021/22) SIS will not conduct outbreak investigations in schools, unless at the request of DHSC and with additional funding provided. In such circumstances PHE will coordinate operational design, building on infrastructure established in the first year of study.

4.4.5 Attendance and Implementation research

4.4.5.1 Year 1:

- Attendance records (Aim 3)

We will collate data from DfE to assess school characteristics, attendance records and information about partial or full school closures over the school year. We will obtain attendance data for participating schools through DfE. This will include both student and staff attendance over the past year, at the start of term and through the year. We will also keep a record of any partial or full school closures.

- Implementation research (Aim 4)

We will assess implementation of preventive measures at schools by engaging four key stakeholder groups: headteachers and senior leaders; teachers and other school staff; parents of students; and students themselves. This will provide an understanding not only of school policies and measures in place, but also their feasibility, acceptability and broader impact.

- Head Teacher Survey

  Head teachers or a nominated substituting other member of SLT will be invited to complete an online questionnaire. This survey will include questions on: guidance received on preventive measures; preventive measures being implemented; challenges and consistency with which these are implemented; facilitators for implementation; policy on school closure; commitment to keeping schools open; effort and preparation that has gone into reopening; ongoing internal assessment of preventive measures at the school; other concerns; head teacher stress; and the acceptability of school preventive measures and our own study. The same survey will be repeated once per term with follow-up surveys being designed so that individuals may quickly report changes from previous survey points.

- Parent survey

  Parents/ guardians of students enrolled in eligible year groups of participating schools will be invited to complete an online questionnaire. This survey will focus

on: preventive measures and challenges, if any, following them for their child; perception of preventive measures and their implementation at school; satisfaction with school communication and approach; lockdown experience; child mental wellbeing (primary school students); personal attitudes towards following recommended guidelines; and acceptability of our own study.

- Student survey

  Participating secondary school students who provide their own informed consent to participate and whose parents/carers do not opt them out of the survey will be invited to complete an online questionnaire. Student views will be sought on: implementation of control measures; adoption and consistency with following recommended control measures; usual contacts before during and after school will be collected; distancing/mixing with other year groups in and outside school; challenges and facilitators to adherence within and outside school; satisfaction with school communication and engagement; lockdown experience; mental wellbeing; school engagement; and experience of our study.

- Staff survey

  All staff at participating schools will be invited to complete an online questionnaire. The survey will include questions on: socio-demographics; preventive measures being implemented; challenges and consistency with which they are implemented; facilitators for implementation; satisfaction with school communication and approach; occupational stress; and acceptability of our study.

- Qualitative research

  Approximately six schools will be purposively selected from participating schools (criteria concerning diversity according to: initial reports of extent of implementation of preventive measures; local deprivation; school type) and we will engage with them longitudinally at two further time points in the course of the year through semi-structured interviews and school diaries. Participants per school will include: head teacher; two staff (purposive by seniority/role); two parents (purposive by gender, initial reports of acceptability); and two students in secondary schools (purposive by gender, initial reports of acceptability). Topics covered will include: experience at school during pandemic; perception and adoption of preventive measures; challenges and facilitators in implementing and using preventive measures; experience with our study; experience with COVID-19; and mental wellbeing. Interviews will be completed by telephone or video conferencing by an experienced social science researcher. For those participants who consent, interviews will be audio recorded and transcribed in full. Prior to obtaining oral consent, participants will be informed about the interview and provided with the opportunity to ask questions. If participants do not agree to being audio recorded, the interviewer will make detailed notes during and after the interview.

4.4.5.2 Year 2:

Implementation research will continue this year, but to some extent be replaced with wider research about the indirect impacts of the pandemic on children. Data collection will expand

to include administrative records collected on the entire school population of England, and questionnaires collected from school children taking part in SIS in 2021/22.

- Administrative records

We will collate data from DfE, NHS England, DHSC and ONS to construct a linked data asset for schools in England. Priority datasets include (but are not restricted to) English School Census, Attendance data, Vaccinations data, Test and Trace (inc. rapid testing), Hospital Episode Statistics, Patient Demographic Service, and 2021 Census.

- Questionnaires

We will provide insight about the broader impacts of the pandemic by engaging three key stakeholder groups: headteachers and senior leaders; parents of pupils up to and including year 11 participating in the study; and secondary school pupils. This will provide an understanding not only of school policies and support services in place, but also pupil experiences of schooling after the first phase of the pandemic.

- Head Teacher Survey:
  Head teachers or a nominated substituting other member of SLT will be invited to complete an online questionnaire. The first survey (autumn term) will include questions on: control measures the schools are still opting to use to minimize infection risk at the school; the extent to which air flow and ventilation guidance can be followed on the school premises, the provision of mental health support services for children. The survey will be repeated once per term with questionnaire content adapted to meet information needs at the time of collection.

- Parent survey:
  Parents/ guardians of pupils enrolled will be invited to complete an online questionnaire. This survey will only retain a subset of questions asked last year, with a focus on the child's health conditions, their COVID test history, and the duration of symptoms children have experienced following COVID infection. Only parents of children up to and including year 11 will be asked to complete this survey.

- Pupil survey
  Participating secondary school pupils who participate in the study will be asked to complete survey modules: mental health; long COVID symptoms and vaccine hesitancy.

- Qualitative research

  We will introduce this research at upcoming Head Teacher forums (already planned under SIS-2). If ethics approval has already been granted by the forum date, we will ask for volunteers to participate in the interviews. If ethics has not yet been approved at the time of the forum, ONS will send a follow up email to all participants inviting them to contact the qualitative researcher to volunteer (see drafted recruitment email in separate document). Ten schools will be purposively selected from participating schools (criteria according to: questionnaire reports of extent of implementation of preventive measures; region; school type) and the Head Teacher of those schools will be invited for an in-depth interview (if the Head Teacher is not available, an alternative member of school leadership staff

designated will be interviewed). We intend to interview 5 primary and 5 secondary Head Teachers, but in the event that it is difficult to recruit 5 from one school type, we will add to the other type to ensure 10 total interviewees. This sample size was chosen as it represents more than 5% of the quantitative sample size, and can reasonably be completed to a high level of quality by the qualitative researcher on this project in the timeframe available. This qualitative work will build on previous qualitative interviews with Head Teachers in 2021. Topics of the interview will include: experiences of the school during the pandemic; perception and adoption of preventive measures; challenges and facilitators in implementing and using preventive measures; pupil and staff mental health provision; managing uncertainty in Covid; other topics may be included based on questionnaire responses. Interviews will take place either using video-conferencing (Zoom or similar) or by telephone, and will be audio-recorded with the consent of the interviewee. It is intended that interviews last no more than 45 minutes, given the time pressures of Head Teachers. Interviews will be transcribed. All participants will be sent a consent form and information sheet prior to the interview, asked to return the signed consent form, and will be given the chance to ask questions and then orally consented prior to starting the interview. If participants would prefer not to be audio recorded, the interviewer will take detailed notes.

4.4.6 Pilot wastewater surveillance

4.4.6.1 Year 1:

As part of the larger UK research on the validity and utility of waste water based sampling (WW sampling) for SARS-CoV2 viral particles, periodic WW samples will be taken within schools that agree to participate. Of these, a random sample of 50 schools will be sampled. Composite WW samples will be collected twice a week from the private drainage system of the school and analysed by Middlesex University and other agencies associated TERM consortium (School wasTE water-based epidemiological suRveillance systeM for the rapid identification of COVID-19 outbreaks) using a standard research protocol. Results from 50 schools participating to both the serology and the TERM project will be used to investigate the relationship (validity, time lags, washout periods) between these samples and sero-incidence and prevalence of infection from a cross-sectional sampling (at end of each half term) of individual schoolchildren in those same schools. As part of the pilot, for a small number (n=3-4) of the schools participating in the TERM project only, where there is evidence of SARS-CoV-2 virus fragments in WW samples but no / limited children COVID19 absences from schools, reactive sampling will be undertaken to estimate the prevalence of infection (via the main study). ONS will be responsible for the main study data collection and analysis. TERM with the Joint Biosecurity Centre will be responsible for the WW sampling data collection and analysis. LSHTM will support analyses with the TERM group, PHE and ONS. Data will be shared across partners (via ONS system).

4.4.6.2 Year 2:

There are no current plans to collect data on waste water and integrate with SIS data sources in 2021/22.

5.0. DATA MANAGEMENT

5.1 Data collection

5.1(a) Year 1:

A secure and government approved software solution will be used for online consent and data collection. IQVIA connect is an established system for collecting personal data and all information collected will be shared securely on a daily basis with PHE and ONS as the data controllers. The results of the nasal swabs from the national testing centre will be linked to participant's survey record and reported to the participant, the school and the national test and trace system. Similarly, the antibody results will be linked to the participant's survey record and reported back to the participant.

Quantitative survey data

Survey data will be managed on secure, password-protected drives. There will be separate files for: unique identification numbers linked to names of schools and individuals; and unique identification numbers linked to survey and any linked data. Analyses will commence with descriptive statistics followed by statistical analyses addressing the research questions.

Qualitative data

Interview data will be transcribed verbatim and in full from audio recordings into MS Word and enhanced with notes taken during the interview. Transcripts will have school, area and individual identifiers removed. Transcripts and notes will be managed and analysed using qualitative data analysis software. A thematic content analysis will be carried out oriented towards answering our research questions. Narrative data will be coded thematically using a deductive approach based on topics covered in the interview guide. Thereafter, a second-level of coding will identify overarching and other new themes from the data, if any, using an inductive approach. Interview data will be stored on password-protected drives or a managed storage environment. Data will be accessed only by the research team directly involved in the study and in the analysis.

5.1(b) Year 2:

We will no longer contract IQVIA to deliver IT systems for questionnaire collection and sample management. All IT systems will be managed directly by ONS teams. A secure and government approved software solution will be used for online consent and data collection. ONS will use SMART Survey as the established system for collecting personal data and all information collected will be shared securely on a daily basis with PHE and ONS as the data controllers. For antibody testing, ONS study workers overseeing sample collections in schools will use M-SOFT to scan anonymised barcode information onto ONS laptops. After dispatching samples for analysis at PHE Colindale, the anonymous antibody results will be linked to the participant's survey record via barcode and reported back to the participant.

Quantitative survey data

Survey data will be managed on secure, password-protected drives. There will be separate files for: unique identification numbers linked to names of schools and individuals; and unique identification numbers linked to survey and any linked data. Analyses will commence with descriptive statistics followed by statistical analyses addressing the research questions.

Qualitative data

Interview data will be transcribed either by an internal member of LSHTM from audio recordings into MS Word. This will be accompanied by any notes taken by the interviewer during the interview. Transcripts will have school, specific geographic and individual identifiers removed. Transcripts and notes will be managed and analysed using qualitative data analysis software (Nvivo) taking a thematic analysis approach. First level coding will be deductive using the interview guide as a framework, second-level coding will take an inductive approach to identify new and overarching themes. Interview data will be stored on password protected drives or a managed storage environment. Data will be accessed only by the research team.

5.1.1 Data Collection and Handling at PHE

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
- General Data Protection Act (GDPR) and Data Protection Act 2018
- Human Rights Act
- Section 3 of the Health Service Regulations 2002
- Section 251 of the NHS Act 2006

5.1.2 Data Collection at ONS

5.1.2.1 Year 1:

ONS will contract IQVIA to develop the online survey platform and the operational delivery of biological testing in schools. Data collected from surveys and biological tests will be received by ONS who will hold the responsibility of linking survey and test results and making consolidated analytical datasets available to researchers within the surveillance team of the study consortium. Anonymised copies of these datasets 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.

All processing of data undertaken by ONS will be performed under and with accordance with the following regulatory frameworks:

- General data protection Regulation and Data Protection Act 2018
- Statistics and Registration Service Act 2007
- Digital Economy Act 2017
- Human Rights Act 1998

5.1.2.2 Year 2:

ONS will develop the online survey platform (SMART Survey) and the operational delivery of biological testing in schools. Data collected from surveys and biological tests will be received by ONS who will hold the responsibility of linking survey and antibody test results and making consolidated analytical datasets available to researchers within the surveillance team of the study consortium. Anonymised copies of these datasets, including a subset of the linked data asset for schools (described in section 4.4.5.2) for all SIS-2 schools, will be linked to questionnaire responses and antibody results and 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.

All processing of data undertaken by ONS will be performed under and with accordance with the following regulatory frameworks:

- General data protection Regulation and Data Protection Act 2018
- Statistics and Registration Service Act 2007
- Digital Economy Act 2017
- Human Rights Act 1998

5.2. ONS Data Access Platform

Survey data and the results of tests collected for the study be will be stored in an ONS Secure Data Platform. ONS has developed an integrated, single environment – the Data Access Platform (DAP) – to host data and facilitate the processing of multiple datasets in richer and more complex forms, including the integration data sources supported by appropriate methods and standards. DAP takes a robust approach to security that is risk-based and holistic, covering people, processes and technology. DAP security is based on two key security governance and management layers. The first layer is a set of security principles to inform design and operation; the second layer distils these principles into specific security controls within the platform. All security controls have been developed following recognised security standards and guidance from within Government, including from the Cabinet Office, the National Cyber Security Centre and the Centre for the Protection of National Infrastructure. They also adhere to international standards and best practice, as set by ISO 27001 and the Information Security Forum. ONS will take responsibility for the data within its platform.

5.3. ONS Secure Research Service (SRS)

After initial processing and linkage in DAP, deidentified versions of datasets (with the exception of the qualitative datasets) will be made available in the ONS Secure Research Service (SRS) to researchers accredited under the Research strand of the Digital Economy Act for accredited research purposes. The SRS will be the central area for analysis to be undertaken by the organisations forming the research consortium for the study; PHE, LSHTM and ONS. All of the research that will be completed will meet the strict safeguards set out in the Research strand of the DEA Research Code of Practice and Accreditation Criteria including a requirement for ethical approval and approval by the Research

Accreditation Panel. Any deidentified data will only be accessed by accredited researchers in the ONS Secure Research Service and all outputs will be disclosure controlled to ensure there is no risk of reidentification and to ensure that the researcher is undertaking the research they have received accreditation for. This will be consistent with the ONS five safes framework which is how ONS make data available to the research community.

5.4. LSHTM Data Security and Storage

Qualitative interview recordings will be securely stored at LSHTM, only accessible to the research team. Zoom (or equivalent software) interviews will be directly recorded to the hard drive of an encrypted and password protected computer. Following completion of the interview, the interview recordings will be uploaded to the LSHTM server and will only be accessible by named members of the research team. LSHTM has an information security policy that is compliant to ISO/IEC 27001 standards. Transcription will be done by a member of the research team. All written transcripts will have personally identifiable information anonymised prior to analysis in Nvivo. School level information will also be anonymized but non-identifiable details will remain (region, school type). Results will be aggregated to ensure no specific school can be identified. Anonymized transcripts will be made available to members of the qualitative research team via the LSHTM server.

5.4. Data analysis and reporting

5.4.1 Year 1:

We aim to provide a summary report of the results of virus testing within 4 weeks of the schools being tested at each sampling point. Analysis will focus on:

- Estimating SARS-CoV-2 virus prevalence in the four groups at enrolment (primary children, primary staff, secondary children, secondary staff), with 95% confidence intervals
- The proportion of schools with at least one case of SARS-CoV-2
- Analysis of the differences in prevalence between high risk areas vs. lower risk areas
- Analysis of the variability in SARS-CoV2 infection at the school level

The first published report is planned for early December and will be hosted on the ONS website.

Virus testing will be conducted at the end of each half-term, with an approximate reporting schedule as follows:

- Virus test 2 (December 2020): reported in February 2021
- Virus test 3 (February 2021): reported in March 2021
- Virus test 4 (April 2021): reported in June 2021
- Virus test 5 (May 2021): reported in July 2021
- Virus test 6 (July 2021): reported in September 2021

Seroprevalence will be reported when the SARS-CoV-2 antibody results become available, with the expectation that lab turnaround will be several weeks. Estimates for SARS-CoV-2 seroprevalence will be produced for the four groups at enrolment (primary children, primary staff, secondary children, secondary staff), with 95% confidence intervals. Analysis of sero-incidence will be provided after each follow up round. Reporting will also include measures of variability across schools and comparisons between schools in higher risk and lower risk areas.

Data on school pupil and staff attendance during the year, including partial and full school closures will support the analysis and feature in reporting. A brief report that summarises findings from each term's implementation questionnaires may also be published.

5.4.2 Year 2:

Antibody testing will be conducted in schools over a 4-5 week period in wave 1, and a 2-3 week period in waves 2 and 3. We aim to produce written reports and analysis soon as possible following data collection, including MI packs for the Government Data Debrief Group and ONS publication bulletins. The proposed dates for antibody collection is outlined below:

- Wave 1: Monday 1st November 2021 to Friday 3rd December 2021

- Wave 2: Monday 10th January 2022 to Friday 28th January 2022
- Wave 3: Monday 7th March 2022 to Friday 25th March 2022

Online questionnaires for secondary pupils and headteachers will be released at around the same time as the start date for each wave of testing. Questionnaire data will be available for analysis prior to antibody test results. For each termly series of questionnaires, we will produce a standalone MI pack and published report summarising analysis of questionnaire modules. We will aim for the following timescales for reporting questionnaire analysis:

- SIS Questionnaires – Report 1: December 2021
- SIS Questionnaires – Report 2: February 2022
- SIS Questionnaires – Report 3: April 2022

Analysis of antibody prevalence in school children will be reported when the SARS-CoV-2 antibody results become available, with the expectation that lab turnaround will be several weeks (possibly up to four months). Estimates for SARS-CoV-2 seroprevalence will be produced for the two groups at enrolment (primary children, secondary children), with 95% confidence intervals at the regional and national level. Analysis of sero-incidence and sero-reversion will be provided after each follow up round. Reporting will also include measures of variability across schools and comparisons between schools across regions. Publication dates will depend on lab processing turnaround, but we will aim to deliver against the following reporting timetable:

- Report 1: National estimate of antibody prevalence in children (wave 1) – Dec 2021
- Report 2: Regional estimates of antibody prevalence in children (wave 1) – Feb 2022
- Report 3: National & regional estimates of antibody prevalence in children (wave 2) – Mar 2022
- Report 4: National & regional estimates of antibody prevalence in children (wave 3) – May 2022

Additional publications will arise from analysis undertaken with the linked schools data asset. These will include analysis of infections using Test and Trace data, the impact of vaccines on school infections and data on school pupil attendance during the year. These analyses may be published in separate bulletins or incorporated into the publications scheduled for SIS questionnaire analysis or the analysis of antibody prevalence.

5.5 Scientific publication of results

The results of detailed analyses will be published in peer reviewed scientific journals and will combine data from across workstreams and questionnaires. The specific titles and research questions to be addressed by scientific papers will be agreed within the Consortium.

6.0. Ethical considerations and ethical approval

This surveillance is being performed as part of PHE's responsibility to investigate the risk and transmission of SARS-CoV2 among children and young people in educational settings. It will also provide crucial information about the prevalence of antibodies in children and the wider impacts of the pandemic on the wellbeing of children. 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 support and protect children and young people 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 has 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 online 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.

6.1. Support for schools taking part in the study

6.1.1 Year 1:

A compensation package will be offered to schools taking part in the study to fund staff activities needed to support the school's effective participation in the study and enable ongoing involvement. The funding package offered will be equivalent to about two full-time administrators' person-time for 30 days for each school.

The study will not prescribe how the package should be used to allow schools the freedom to spend the funds in the way most appropriate to their circumstances, to support the study's activities. However, schools will be prohibited to use the compensation to offer any direct payment (monetary or other) to staff, parents, or pupils, to incentivise participation to the study. Examples of appropriate use of the compensation funds include:

- Printing and distribution of SIS campaign materials
- Promoting the study with pupils in classrooms
- Engaging parents through school social media and other channels of communication used by the school
- Supporting paper enrolment and questionnaire completion by providing assistance to parents for whom English is an additional language or where there may be limited computer access
- Paying for translation and/or interpreter services
- Inputting data from paper enrolments into SIS computer-based data collection systems
- Preparing for onsite SIS testing, including cross checking participant sign ups with the school
- Coordination between the school and the study team during onsite testing

The compensation package will not be contingent on achieving any recruitment target or performance within the school. Schools will be encouraged to commit to activities to support the study, in good faith, and to liaise regularly with the study engagement officers to discuss initiatives they are using in the school and seek further advice.

To initiate the compensation process, engagement officers will discuss the offer with each of their designated schools, and will send a confirmatory email to schools summarising the initiatives schools have verbally agreed to roll out. These emails will serve as a record and will trigger the release of funds in one tranche. There will be no requirement for schools to document spend.

6.1.2 Year 2:

A revised compensation package will be offered to schools taking part in the study to fund staff activities needed to support the school's effective participation in the study and enable ongoing involvement. Compensation payments of £1000 will be made to schools following completion of each test wave that the school participates in. With three test waves scheduled between November 2021 and March 2022, schools taking part throughout the

duration of the study will qualify for a total compensation package of £3000. Schools must accommodate testing to take place onsite to qualify for compensation payments. Schools are also expected to actively support promotional activities to recruit participants and increase enrolments throughout the study.

The study will not prescribe how the package should be used to allow schools the freedom to spend the funds in the way most appropriate to their circumstances, to support the study's activities. However, schools will be prohibited to use the compensation to offer any direct payment (monetary or other) to parents, or pupils, to incentivise participation to the study. A separate offer of compensation will be made to secondary school pupils, directly from the study team (see 6.1.3 below). The same examples described in 6.1.1. will be considered appropriate use of the compensation funds in this year's study.

The compensation package will not be contingent on achieving any recruitment target or performance within the school. Schools will be encouraged to commit to activities to support the study, in good faith, and to liaise regularly with the study engagement officers to discuss initiatives they are using in the school and seek further advice.

To initiate the compensation process, engagement officers will discuss the offer with each of their designated schools, and will send a confirmatory email to schools summarising the initiatives schools have verbally agreed to roll out. These emails will serve as a record and will trigger the release of funds in one tranche. There will be no requirement for schools to document spend.

6.1.3 Pupil Compensation (Year 2 only)

To maximise student participation and high response rates to secondary school pupil questionnaires we are offering £5 compensation to children for their time spent taking part in each of the three questionnaires (total of £15 for completing all three). Payments will be made by e-voucher, directly to children using the contact details provided at registration. Each payment will be made soon after completing the questionnaire. Parents will be informed of this arrangement when registering children in years 7 to 11 and will agree to this as part of the parental consent declaration.

6.2. Withdrawal of Participants

6.2.1 Year 1:

Staff and parents/guardians of participating students and students themselves 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 will not be affected in any way. They can do this by sending an email to a designated mailbox which will be monitored by the study team for appropriate action. The withdraw procedure will require inclusion of the participant's name and date of birth.

6.2.2 Year 2:

The same procedure for withdrawal will be followed in this year's study, but with the withdrawal activities monitored and actioned by ONS teams. Withdrawals will only apply to pupil participants since staff are no longer invited to take part in the study.

6.3. Participant Confidentiality

6.3.1 Year 1:

Personal data collected for the purposes of this surveillance includes name, date of birth, post code, contact details 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. IQVIA Connection is hosted in a secure datacentre in England. The online questionnaire is hosted on a secure HTTPS connection and data are encrypted at the point of transmission and stored at rest on the server. Data will only be used for the purposes of this study, stored in secure datacentre facilities on 256-bit encrypted servers with restricted access. Data collected by the study will be treated as strictly confidential and handled in accordance with the General Data Protection Act (GDPR) and Data Protection Act 1998, Caldicott guidelines, Section 251 of the NHS Act, an ISO27001 Information Security Management System and NHS Data Security and Protection Toolkit requirements. Data will be shared within the surveillance team so that the stated objectives and reporting commitments can be achieved.

6.3.2 Year 2:

The same confidentiality principles laid out in 6.3.1 will apply in year 2, with IQVIA connection being replaced with Smart Survey. Smart Survey is also hosted in a secure data centre in England, with secure hosting and encryption at the point of transmission.

The questionnaires for secondary school pupils will include modules on mental health and personal wellbeing. The questionnaire content is likely to change between each release, and the study team will review duty of care requirements if response categories are likely to be indicative of children at considerable risk (e.g., severe depression or self-harm). Before releasing questionnaires to pupils, we will review the survey content in line with the ONS Safeguarding Policy. Where a duty of care disclosure (i.e., an obligation to notify parents or staff of a child at risk) is a possibility, we will ensure that children are advised in advance in accompanying survey information that in exceptional circumstances we may be obliged to share some of the information provided in their questionnaire responses.

Participants may also feel distressed from completing questionnaires relating to their mental health and/or report serious symptoms that put them at immediate risk. The research team will provide information on where to seek support and provide self-help information. Unfortunately, the researchers are unable to provide medical advice and responses are not analysed immediately. However, existing national surveys of children's mental health also follow this risk protocol.

6.4. Patient and Public Involvement (PPI) - Year 1 only

A focus group session consisting of eight adolescents from school years 10 to 13 took place to gather their thoughts and first impressions about the study. The majority of the teenagers expressed eagerness to return to school and therefore, found the study research question of utmost importance. Concerns about getting infected and passing the disease to an "at-risk"

relative or unknown person was a primary preoccupation. There was a willingness across the group to contribute and help further current COVID-19 understanding, and the participation's requirements weren't perceived as an over-ask. There was nonetheless a little concern about sample storage which once explained seemed acceptable to them.

7.0 TARGET DATES

7.1 Year 1:

- ***Recruitment to commence:*** 12 October 2020
- ***Completion of recruitment***: 31 July 2021
- ***Completion of surveillance:*** All sampling will be completed within 12 months and surveillance within 24 months

7.2 Year 2:

- ***Recruitment to commence:*** 8th October
- ***Completion of recruitment***: 22 March 2022
- ***Completion of surveillance:*** All sampling will be completed within 12 months and surveillance within 24 months