Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)

Version: 1.1 Date: 30 September 2020 Contact: <u>EarlyInvestigations-2019-nCoV@who.int</u>



#### **Reference:**

The emergence of a new virus means that understanding transmission patterns, severity, clinical features and risk factors for infection will be limited at the start of an outbreak. To address these unknowns, WHO has provided protocols for special investigations in different settings.

Data collected using these investigation protocols will be critical to refine recommendations for case definitions and surveillance; characterize key epidemiological features of COVID-19; help understand the spread, severity and spectrum of disease and impact on the community; and inform guidance for application of countermeasures such as case isolation and contact tracing. These protocols are designed to enable the rapid and systematic collection of data in a format that facilitates comparison across different settings globally.

They are available on WHO website here: <u>https://www.who.int/emergencies/diseases/novel-</u> coronavirus-2019/technical-guidance/early-investigations

COVID-19 investigations and study protocols <u>available</u> include:

1. The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)

2. Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)

**3.** Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting: cohort or case control designs

4. Population-based age-stratified seroepidemiological investigation protocol for coronavirus 2019 (COVID-19) infection

5. Surface sampling of coronavirus (COVID-19) virus: a practical "how to" protocol for health-care and public health professionals

6. Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)

Please contact <u>earlyinvestigations-2019-nCoV@who.int</u> for any questions.

All WHO protocols for COVID-19 are available on the <u>WHO website</u> together with the technical guidance documents.

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#### Summary

Schools and other educational institutions investigation protocol				
	for coronavirus disease 2019 (COVID-19).			
Population	Students and staff of schools and other educational institutions with			
	a laboratory-confirmed case of COVID-19			
	d The overall aim is to rapidly and systematically collect data to gain			
analysis	an understanding of the transmission dynamics of COVID-19			
	infection among cases and contacts within schools and other			
	educational institutions.			
	Primary objectives are:			
	<ul> <li>to estimate infection rates for overall and secondary SARS-</li> <li>Col/ 2 infections in the school setting</li> </ul>			
	CoV-2 infections in the school setting			
	<ul> <li>to estimate the secondary clinical attack rate of SARS-CoV-2 in this setting</li> </ul>			
	• to estimate the fraction of asymptomatic SARS-CoV-2			
	infections within schools and other educational institutions			
	• to describe the epidemiological and clinical characteristics of			
	primary and secondary cases of COVID-19			
	• to identify potential risk/protective factors associated with			
	the SARS-CoV-2 infection risk.			
	The secondary objectives are:			
	• to estimate the incubation period of SARS-CoV-2 and the			
	duration of infectiousness and of detectable shedding;			
	• to estimate the serial interval of SARS-CoV-2 infection in			
	this setting;			
	• to estimate the reproduction numbers: <i>R</i> <sub>0</sub> and <i>R</i> of SARS-			
	CoV-2 in this setting; and			
	<ul> <li>to characterize the serological response following</li> </ul>			
	confirmed COVID-19 infection.			
Design	Prospective case-ascertained investigation of school contacts of a			
	laboratory-confirmed case of COVID-19.			
Duration	Post-identification of school contacts of the first laboratory-			
	confirmed case(s), the investigation will continue until no laboratory-			
	confirmed COVID-19 cases are detected among the contacts of			
	confirmed cases in the school setting.			
Recruitment	School contacts of laboratory-confirmed primary case(s) will be			
	invited to participate in the investigation according to			
	predetermined country-specific sampling strategy.			
	<b>Id</b> • Data collection: epidemiological data, including basic			
specimens to be obtain	obtained demographics and clinical characteristics			
from participants	primary/secondary/subsequent cases and contacts; and school			
	characteristics.			
	• Specimens: respiratory and blood (and/or saliva samples, when			
	validated saliva tests become available).			

Comments for the user's consideration are provided in purple text throughout the document, as the user may need to modify methods slightly because of the local context in which this investigation will be carried out.

# 1. Background

#### 1.1 Introduction

Coronavirus disease 2019 (COVID-19), first reported from Wuhan city, China in December 2019 (1), was declared by World Health Organization (WHO) Director-General a Public Health Emergency of International Concern on 30 January 2020 and described as a pandemic on 11 March 2020. The etiological agent of COVID-19, severe respiratory syndrome coronavirus 2 (SARS-CoV-2), is primarily transmitted between people through respiratory droplets and contact routes: direct contact with infected people and indirect contact with surfaces in the immediate environment or objects used on an infected person. Airborne transmission may also be possible in aerosol-producing circumstances. Asymptomatic and pre-symptomatic individuals are able to transmit infection.

Available evidence to date suggests that children and adolescents may be less susceptible and present with a less severe clinical course than adults. A meta-analysis of contact tracing studies (2) reported that for all studies, children were less likely to become infected as a contact than adults for all studies (odds ratio [OR], 0.44; 95% confidence interval [CI], 0.29–0.68; n = 8;  $l^2 = 63\%$ ), regardless of whether studies included household-only contact tracing (OR, 0.19; 95% CI, 0.10–0.37; n = 3;  $l^2 = 0\%$ ) or all close contacts (OR, 0.63; 95% CI, 0.50–0.80; n = 5,  $l^2 = 0\%$ ). There is little/no published evidence on how transmissible children may be compared to adults. Early cluster investigations in France (3), Ireland (4) and Australia (5) suggested that children were not associated with significant transmission in schools. However, in a serologic investigation of a high-school cluster in France prior to enforcing social distancing measures (6), the infection crude attack rates were 92/240 (38%) in pupils of high school age, 23/53 (43%) in teachers and 16/27 (59%) in school staff (overall response rate = 58%). In the same study, the proportion of seropositive individuals among asymptomatic participants in the study was 14% (29/209).

Although COVID-19 is considered less severe in children, there are recent reports from Europe and North America of an increased number of cases of severe paediatric multi-system inflammatory syndrome with features of Kawasaki disease and toxic shock syndrome since the beginning of the COVID-19 pandemic. The causal relationship between this severe disease in children and adolescents and SARS-CoV-2 infection is still being investigated (7).

For the COVID-19 pandemic response, WHO has defined four transmission scenarios for COVID-19 (8):

- 1. countries with no cases (No cases);
- 2. countries with one or more cases, imported or locally detected (Sporadic cases);
- 3. countries experiencing case clusters in time, geographic location and/or common exposure (Clusters of cases); and
- 4. countries experiencing larger outbreaks of local transmission (Community transmission).

Many countries implemented large-scale public health and social measures (PHSM) according to these transmission scenarios, including closure of schools and other educational intuitions to minimize the risk of transmission between adult staff and children and adolescents. WHO recommends adjusting these measures according to the evolving disease transmission pattern in the country (9). As of 13 May 2020, according to the United Nations Educational, Scientific and Cultural Organization (UNESCO), 65 countries plan for partial or full reopening of schools, 32 ended the academic year online and 100 countries have not announced a date for school reopening (10). The International Red Cross Federation, United Nations Children's Fund (UNICEF) and WHO issued early guidance for safe operations through the prevention, early detection and control of COVID-19 in schools and other educational facilities, specifically to countries that have already confirmed the transmission of SARS-CoV-2 (11).

Following school re-opening before the 2020 summer school holiday, no major rises in the COVID-19 cases were reported in 22 European Union countries (12); however, large school outbreaks were reported in some countries (Israel, South Africa, etc.) (13, 14). Since then, sporadic cases have been reported from schools in several European Union countries and schools were closed in parts of the United Kingdom of Great Britain and Northern Ireland and Germany for example, because of increases in cases. In addition, given the higher rates of disease seen in adults, the risk to teachers and other adult staff in schools has raised questions around the potential for disease transmission in schools that warrant continued consideration.

This protocol provides guidance for investigating transmission of SARS-CoV-2 in schools and other educational institutions. The protocol should be adapted and used locally, however the use of a standardized methodology enable results to be compared. At the national level, the ability of public health and educational authorities to enact these studies can also provide more locally relevant, contextual evidence on the policies and practices implemented, and timely information on updating or scaling up public health measures in this setting.

## 1.2 Considerations before starting an investigation

A COVID-19 school transmission investigation is triggered by identification of a confirmed case in a school or educational institution. Before starting the investigation, the public health authorities should define the geographic scope of this investigation (local, regional, national) and become aware of different surveillance initiatives and available public health practices in schools and other educational institutions within their jurisdiction.

Seeking cooperation and actively involving the local education authorities, schools' management and medical staff, parents' associations and parents themselves in the investigation will be of paramount importance for the efficient and smooth implementation of the investigation.

At this stage of the pandemic, many countries have activated or set up a multisectoral response strategy, including steps and plans for safe operation of educational facilities to be undertaken when a staff member or student become sick or tests positive for SARS-CoV-2. The school transmission investigation should be planned and coordinated with the response, taking into account the COVID-19 surveillance strategy and transmission scenarios in the community, as recommended in the latest WHO guidance (8, 15).

# 1.3 Objectives

The overall aim of this protocol is to rapidly and systematically collect data to gain an understanding of the transmission dynamics of SARS-CoV-2 infection among cases and contacts within schools and other educational institutions (including kindergartens, pre-schools, nurseries, boarding schools, vocational schools, etc.).

The **primary objectives** of this investigation among cases and contacts within schools and other educational institutions are to collect data to enable:

- estimates of infection rates for overall and secondary SARS-CoV-2 infections in this setting;
- estimates of the secondary clinical attack rate of SARS-CoV-2 infection in this setting;
- estimates of the fraction of asymptomatic SARS-CoV-2 infections within schools and other educational institutions;
- to describe the epidemiological and clinical characteristics of primary and secondary cases of COVID-19; and
- to identify potential risk/protective factors associated with SARS-CoV-2 infection risk.

#### The secondary objectives are:

- to estimate the incubation period of SARS-CoV-2 and the duration of infectiousness and of detectable shedding;
- to estimate the serial interval of SARS-CoV-2 infection in this setting;
- to estimate the reproduction numbers: R<sub>0</sub> and R of SARS-CoV-2 in this setting; and
- to characterize the serological response following confirmed SARS-CoV-2 infection.

For the purpose of understanding transmission in the school setting and addressing the primary objectives stated above, the scope of this protocol is restricted to the school setting. That is, the protocol does not address the further transmission from school to household, or household to school. Investigation teams interested in understanding transmission dynamics in the school and household settings are encouraged to adapt the investigation using the household transmission protocol (16).

#### A reminder of some definitions of epidemiological terms:

- In this context, the **secondary infection rate** is a measure of the frequency of new **infections** of SARS-CoV-2 among contacts of confirmed cases in a defined period of time, as determined by a positive SARS-CoV-2 test result. *In other words, it is the rate of contacts being infected, assessed through polymerase chain reaction (PCR)/serological assays on paired samples.*
- The **secondary clinical attack rate** is a measure of the frequency of new symptomatic **cases** of SARS-CoV-2 infection among the contacts of confirmed cases in a defined period of time, as determined by a positive SARS-CoV-2 result. *In other words, it is the rate of clinical manifestation of the infection in contacts.*
- The **serial interval** is defined as the period of time from the onset of symptoms in the primary case to the onset of symptoms in a contact case.
- The **basic reproduction number** *R*<sub>0</sub> is defined as the number of infections produced, on average, by an infected individual in the early stages of the epidemic, when virtually all contacts are susceptible. Note that it can be assumed that there will be limited immunity to SARS-CoV-2.
- The **incubation period** is defined as the period of time between an exposure resulting in SARS-CoV-2 infection and the onset of the first clinical symptoms of the disease (*from infection or exposure to disease*).
- The **duration of infectiousness** is the time during which virus is shed and transmissible, regardless of clinical symptoms.
- It is currently not known how long detectable SARS-CoV-2 shedding lasts; information from this study would help to clarify the **duration of detectable shedding** among individuals with confirmed infection.

#### 1.4 Coordination of the investigation

Coordination of investigations and sharing of information in real-time will be needed at country level. Epidemiologists, modelers, virologists, nurses, statisticians, clinicians and public health experts will all assist in developing early estimates of key clinical, epidemiological and virological parameters of the SARS-CoV-2 virus. Table 1 shows the roles and responsibilities involved for Country X.

Table 1. Coordination matrix of roles and responsibilities in Country X

What?	Who?
Overall coordination of the early investigation	[Cite institution/ body/person(s)]
Case detection, informed consent, enrolment investigation	[Cite institution/ body/person(s)]
Contact identification, informed consent, enrolment and follow-up	[Cite institution/ body/person(s)]
Laboratory testing and storage of samples	[Cite institution/ body/person(s)]
Analysis of data	[Cite institution/ body/person(s)]
Data management	[Cite institution/ body/person(s)]
IT management	[Cite institution/ body/person(s)]
Informing participants of their individual results and communication of overall findings of investigation to the community and health authorities	[Cite institution/ body/person(s)]
[add more roles, as per country context]	[Cite institution/ body/person(s)]

The school transmission investigation will be maintained centrally by [cite institution/body/person(s)]. Centralized coordination will require development of a "command and control" plan, to allow for triage and prioritization of investigations.

# 2. Methods

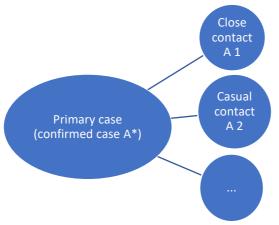
#### 2.1 Design

This investigation is a prospective case-ascertained study, which may also be referred to as a **school-based transmission investigation**. Participants are identified from those with laboratory-confirmed infection, which is distinct from a cohort study in which a group of disease-free participants are recruited and then followed over time (see Fig. 1). Case-ascertained transmission studies are more efficient than cohort studies when interest is in early ascertainment of the clinical, epidemiological and virological characteristics of an emerging virus. This is because the risk of primary or secondary infection in a "sleeping" cohort would be expected to be low during the early stage of the pandemic before widespread community transmission is established.

This is a prospective investigation that will be performed in parallel with the country public health response to the management of COVID-19 cases in the country.

COMMENT: The approach outlined here is for the investigation to be conducted prospectively when the first case detected in the school is the primary case. If one or more generations of cases are detected in the school at the initial investigation (possible in case of a widespread transmission in the community), retrospective data on the contacts should be collected and serology testing proposed.

#### Fig. 1. The chain of transmission in a school transmission study



\*Primary case could be a student or member of staff (teaching or non-teaching staff).

#### 2.2 Population

The population under consideration is all students and staff of participating schools or other educational institutions (including kindergartens, pre-schools, nurseries, boarding schools, vocational schools, etc.). This investigation needs to be conducted in institutions which are able to conduct the investigation effectively.

Priority will be given to institutions in which a laboratory confirmed case of COVID-19 is identified. This in itself will be challenging as children, particularly children under 10 years of age tend to have mild or asymptomatic disease compared to adults.

**Inclusion criteria**: All children and staff are eligible to be recruited in the investigation if present in the school during the period of infectiousness of the primary case.

**Exclusion criteria**: Refusal to participate at school level, refusal to give informed consent at individual level, or contraindication to specimen collection. Students and staff absent from school during the infectiousness period of the primary/co-primary case(s) will be excluded from the investigation.

COMMENT 1: Efforts should be made to include students and staff who are absent from school during the investigation if they were in school during the primary/co-primary case(s) infectiousness period.

COMMENT 2: Previously confirmed cases are not to be excluded from the investigation population. They may need to be excluded at the advanced analytics stage.

#### 2.2.1 Case definitions

**Case definitions** for COVID-19 reporting are available on the <u>WHO website</u> (17), although they are subject to further updates as more information becomes available. Country case definitions for COVID-19 are described in Box 1.

#### Box 1. Country COVID-19 case definitions (check the <u>WHO website</u> (17) regularly for any updates) Suspected case

COMMENT: To be completed by the country

#### Probable case

COMMENT: To be completed by the country

#### **Confirmed case**

COMMENT: To be completed by the country

#### 2.2.2 Contact definitions

**Contacts** are defined in accordance with the WHO technical guidance: <u>Contact tracing in the context of</u> <u>COVID-19</u> (18). Check the <u>WHO website</u> (17) regularly for any updates. For the purpose of this school transmission protocol, the interim contact definitions for COVID-19 presented in Box 2 are proposed.

Box 2. Interim contacts definition and classification for the purpose of the COVID-19 school and other educational institution investigation protocol

For the purpose of this protocol, contacts will be defined as close contacts or casual contacts.

#### **Close school contact**

Any student or member of school staff who was in the same closed and confined environment as, OR had direct physical contact with:

- a confirmed COVID-19 case in the school setting (facility or school transport) during their symptomatic period, as well as 2 days before symptom onset and the 14 days after the onset of symptoms in the primary/co-primary case; or
- a confirmed <u>asymptomatic</u> COVID-19 case, with the period of exposure being 2 days before the case was sampled, to 14 days after the date on which the sample that led to confirmation was taken.

(Examples of close contact include: classmates who shared at least one class with the primary case; teachers who gave lectures in the class of the primary case; members of the same study group; colleagues who had at least one class with the primary case; shared study material with a primary case; indoor activities in the same group, such as music classes/choir; outdoor activity in the same group, such as common recess of same or different grades' children; same transportation; etc.)

#### **Casual school contact**

Any person present in the school during the exposure period (2 days before to 14 days after onset of symptoms in the primary case) of the primary case and not qualifying as a close contact.

(Examples of casual contact include: casual encounter or passing with the primary case; outdoor activity not in the same group, such as a recess but which took place at a different time that the recess the primary case attended; etc.)

COMMENT: Asymptomatic confirmed cases may have been infected up to 14 days before sample collection. The definition above is proposed in accordance with the WHO technical guidance. Data informing these assumptions are regularly updated and investigators should review WHO guidance when preparing the investigation protocol. Check the WHO website regularly for any updates and especially the WHO guidance on <u>Contact tracing in the context of COVID-19</u> (18).

#### 2.2.3 Further definitions

**Primary cases** are defined according to the WHO case definition (17). Confirmed cases with onset dates less than 24 hours from the date of symptom onset of the primary case are considered to be **"co-primary" cases**, based on a context where they both attended school while infectious.

**Secondary cases** are defined as cases confirmed by molecular testing and/or serology compatible with recent infection, according to following situations:

- onset of symptoms (symptomatic) or date of specimen collection (asymptomatic) 24 hours or more after the symptom onset of the primary case(s) (symptomatic primary case); or
- onset of symptoms (symptomatic) or date of specimen collection (asymptomatic) 24 hours or more after the date of specimen collection of the primary case (asymptomatic primary cases); AND
- no other plausible likely alternative source of infection than the primary/co-primary case(s) in the school setting.

**Setting**: For the purpose of this protocol, any educational institution that gathers students and staff in an institutional environment can be included (schools, kindergartens, pre-schools, nurseries, boarding schools, vocational schools, etc.), hereafter generically referred to as "schools". With appropriate modifications, this protocol could be adapted for use in university or special education settings.

COMMENT: The **age groups** covered by these educational institutions depend on the organization of the education system in the country and should be specified in the country-specific protocols.

**Symptomatic cases** are primary/co-primary and secondary and subsequent cases with at least one symptom from the list detailed in case form (Form A1) presenting any time before the date of specimen collection.

**Asymptomatic/pre-symptomatic cases** are primary/co-primary and secondary and subsequent cases with no symptoms any time before the date of specimen collection for confirmatory test (NAAT and/or serology compatible with recent infection).

**Past infections** (serology definitions) are contacts with a first serology test (Day 1 at the investigation) indicating IgG detection in the absence of other markers of recent infection.

**Period of infectiousness** is defined as the period of time when the primary/co-primary cases can transmit the disease, as currently accepted: from 2 days before to 14 days after the onset of illness (symptomatic cases) OR from 2 days before the case was sampled, to 14 days after the date on which the sample, which led to confirmation, was taken (asymptomatic cases) (18).

COMMENT: The school transmission investigation should be corroborated with additional studies conducted by the public health authorities involving children and adults included the current studies (e.g. household transmission investigation, health-worker risk factors studies [for school medical staff], seroprevalence studies).

#### 2.2.4 Population enrolment

#### Schools enrolment

Priority will be given to institutions in which a laboratory confirmed case of COVID-19 is identified.

A representative from the **school** will be asked whether they are able to conduct an investigation when the first confirmed COVID-19 case is identified in at least one individual who attended/worked in the school during the period of infectiousness. If the school is able to conduct the investigation and once a primary case or a cluster of cases is identified in the school, the investigation team will identify eligible participants, gather informed consent/assent from eligible participants and start contact tracing activities, so that students and staff are followed up to identify co-primary and secondary and subsequent infections.

Recruiting institutions will be required to put in place effective consent processes and these will include a requirement to ensure that potential participants are not asked for consent/assent in circumstances in which it would be difficult for them to say no e.g. they should not be invited to participate by someone who is in a relationship of authority to them. Equally, there should be no professional, academic or health impact if any eligible individual refuses to participate in the investigation.

#### Identification of primary cases

In this investigation, primary cases will be identified through either:

- existing surveillance systems at the local/national level (4): notifications of laboratoryconfirmed cases with recent infection (e.g. general practitioners, paediatricians, laboratories, special COVID-19 clinics, hospitals, etc.); or
- school-based surveillance: school-based active syndromic surveillance systems are encouraged. These are based on parents reporting (through apps, text messages) reasons for absenteeism, daily symptoms, daily notifications as described for influenza surveillance (20–22), or symptom screening at the school level, and trigger the investigation once an individual has tested positive for SARS-CoV-2 infection.

COMMENT: Primary case identification may differ among countries according to the surveillance practices. Special efforts should be made to start investigation of primary cases in schools as early as possible, to rapidly identify the school contacts and interrupt the transmission in the school and the community.

#### Contact identification

Once a case is detected in the school:

- a **representative from the school** will be asked whether they are able to conduct an investigation when the first confirmed COVID-19 case is identified in at least one individual who attended/worked in the school during the period of infectiousness. Cases should be isolated and contacts quarantined, in accordance with national public health guidance.
- **the school** should provide a list of all students (by grade, class, group activities) and staff (teachers, medical, administrative, other) to the investigation team. Class planning should also be provided for the students identified as close and casual school contacts;
- all information provided to the investigation team, either by the school or by any of the participants needs to be stored securely and to ensure confidentiality at all times;

- an investigation team working with the public health authority will contact all known **close and casual school contacts** of a primary case(s) identified by the school and invite them to participate in the investigation.
- identified school contacts should report to the relevant health authorities any signs and symptoms compatible with SARS-CoV-2 infection, as per local protocols for contact tracing and management;
- any contact with clinical symptoms within 14 days of the last exposure/contact with the primary case(s) should be considered a **suspected case**, and therefore managed according to national/local case management protocols; and
- contacts who are found to be infected with SARS-CoV-2 should be reclassified as **cases** and followed up as cases.

COMMENT: If the investigation continues during the period of widespread community transmission when a large number of eligible primary cases may be detected in participating schools, it may be unfeasible to follow up contacts, due to limitations of resources and capacity. Therefore, a sampling strategy should be defined to minimize selection bias. This sampling strategy should also take into account the clustering of cases and ideally ensure that larger clusters are not overrepresented in the investigation.

These studies will be resource intensive, as there is likely to be a large number of contacts per confirmed primary/co-primary case. It is recommended to prioritize the inclusion of close contacts, and where resources allow to also include casual contacts and subsequently all school contacts. Focusing on close contacts assumes that those with higher exposure to primary/co-primary case(s) are included. If only close school contacts will be included, the investigators should ensure that all close school contacts are identified, to avoid underestimation or overestimation of the secondary attack rates.

Non-school contacts of primary/co-primary case(s) (e.g. in the household, playground, etc.) should be followed as part of regular contact tracing efforts at the local level. Additional protocols are available for the household contacts and other defined populations or settings (23).

#### 2.3 Duration

The duration of the investigation may vary depending on the characteristics and transmission dynamics of the virus in the community where the school is located.

Enrolment in the investigation will begin with identification of the initial laboratory-confirmed COVID-19 case(s) in a school-aged child or member of school staff and will continue ideally until no laboratoryconfirmed COVID-19 cases are detected among the contacts of the last generation of confirmed cases related to the school (see Fig. 2).

COMMENT: The implementation of this protocol should take into account the transmission scenarios in the community and be corroborated with public health measures and protocols for case management, contact tracing and cluster investigation at the local level.

#### 2.4 Data collection

#### 2.4.1 Summary

Interviews will be conducted with primary/co-primary case(s) who has provided informed consent/assent (Forms A1 and A2), contacts who have provided informed consent/assent (Forms B1 to B3) and management personnel from the school who have provided informed consent (Form C1), to collect demographic, clinical and exposure information (see Table 3).

Note that these questionnaires are not exhaustive and may need to be adapted to the local setting and epidemic characteristics, but they provide the investigation team with an outline of the data to be collected for investigation participants. Interviews with the primary/co-primary cases should be used to refine the questionnaires for the contacts.

COMMENT: For children and staff currently receiving medical care for SARS-CoV-2 infection and who have provided informed assent/consent either directly, or by proxy, a family member /guardian will be asked to complete the questionnaire on their behalf.

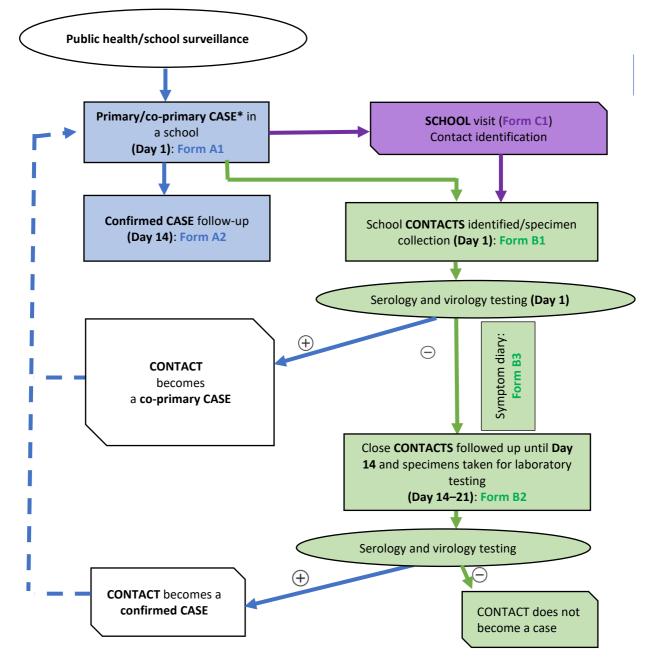


Fig. 2. School investigation algorithm and summary of data-collection tools

\*This will be the index (i.e. first notified) case in school in most situations. If a prior generation of cases is retrospectively identified, they should be reclassified as the "primary case(s)", and if still appropriate have contacts identified and followed up.

Form			
number	Purpose of form	Collecting from whom?	When should it be collected?
CASES			
Form A1	Case <b>initial</b> reporting form	For primary/co-primary COVID-19 cases and secondary and subsequent cases	As soon as possible after laboratory confirmation of a case (Day 1).
Form A2	Case follow-up reporting form	For COVID-19 cases (primary/co-primary and secondary and subsequent cases): final outcome	14 days after completion of Form A1, which is approximately 21 days after initial symptom onset of the case (Day 14). Updates should be sought regularly, if all the required information is not available at the time of completing this form.
CONTACTS			
Form B1	Contact initial reporting form	For close/casual contacts of confirmed COVID-19 cases	As soon as possible, ideally within 24 hours after laboratory confirmation of the primary case (Day 1).
Form B2	Contact <b>follow-up</b> reporting form	For close/casual contacts of confirmed COVID-19 cases: final outcome	14 days till 21 days after completion of Form B1 (Day 14–21).
Form B3 – Symptom diary	Record the presence or absence of various signs or symptoms	For close/casual contacts of confirmed COVID-19 cases	For <b>14 days</b> after administration of the initial Form B1 questionnaire
Schools			
Form C1	School reporting form	School director/ medical staff	As soon as possible, ideally within 24 hours after laboratory confirmation of the primary case ( <b>Day 1</b> ) and every time a secondary/subsequent case is detected in the school.

#### Table 3. Summary of data-collection tools

#### 2.4.2 Cases

Each **primary/co-primary case** (or their parent/legal tutor/guardian for children) who has provided assent/consent either directly, or by proxy, should be asked to complete a **questionnaire** (Form A1) as soon as possible after confirmation (Day 1: baseline visit and virological and serological testing). Primary/co-primary cases will be followed up at Day 14, using Form A2.

COMMENT: The visit should start by asking for the class schedule or activities (if a staff member) of the primary case and adaptation of the questionnaire related to exposure.

#### 2.4.3 Contacts

After their identification, close and casual school contacts (or their parent/legal tutor/guardian for children) will be invited to participate in the investigation. Contacts accepting participation will be invited to respond to a questionnaire at Day 1 (Form B1) and provide samples for testing. If contacts do not develop symptoms during the 14 days of follow-up, a follow-up questionnaire will be administered between Days 14 and 21 (Form B2) and virological and serological testing will be performed.

Symptom diaries (Form B3) (template available in Appendix A of this protocol) will be provided for all contacts, to document the presence or absence of various signs and symptoms. The diary should be completed for 14 days after the administration of the baseline questionnaire.

Any contact with symptoms within 14 days of the last exposure/contact with the primary case should be considered a symptomatic contact and tested. The symptomatic contact should be considered a **suspected case** until the laboratory results become available. Contacts with positive test for SARS-CoV-2 will be re-classified as **confirmed cases**. Contacts, suspected and confirmed cases should be managed according to local case management guidelines.

COMMENT: As mentioned above, in case of limited resources, data collection from school contacts should be initially restricted to close school contacts unless resources allow further investigation of casual contacts. The symptom diary and epidemiological information can be collected through post, apps, text messages or online chats/emails, or other supplementary data from clinics' records for symptom information may be used.

#### 2.4.4 Schools

Following detection of primary cases, the investigation team will visit the school to identify the contacts, collect relevant information and prepare testing for identification of co-primary/secondary or subsequent cases as well as past infections. Information on the school and mitigation measures in place will be collected according to **Form C1**. This baseline school visit should be conducted as soon as possible after identification of the primary case (ideally within 1–2 days of laboratory confirmation of the primary case) and each time a new cluster is identified).

COMMENT: In the context of a COVID-19 epidemic, when it may not be feasible to conduct school visits and to take specimens from school contacts at the school facility, the investigation team should recommend a visit to a central location for specimen collection or provide the possibility of self-swabbing or swabbing at home to collect respiratory specimens. Self/parent-swabbing, which is also used for other respiratory infections (24), may be a valid alternative for virological confirmation (25, 26), but requires pre-planning, transport and training provided to participants.

The steps involved in implementation of the school investigation are summarized in Table 4.

## Table 4. Steps of school investigation implementation

A. Preparation pha				
		/regional context		
<ul> <li>Adapt the protocol for the national/regional context</li> <li>Obtain permissions from the relevant educational structures</li> </ul>				
	th the public health a			
	•			
	ation on the investig	ation and increase awareness in schools		
B. Initial steps	Cotting/load	A stivity	Timeline	
Step 1.Identification of	Setting/lead Public health and	Activity	Continuously	
primary case(s)	school	<ul><li>Daily contact with public health authorities</li><li>Daily reporting of the school(s)</li></ul>	during the school	
	surveillance		operation	
2. Interview of	Home/ health	• Explain investigation to individuals (and	Day 1 (Form A1)	
primary cases	facilities	parent/guardian), obtain informed		
identified		consent/assent		
		<ul> <li>Record information on Form A1</li> </ul>		
		Obtain information on specific contacts in		
		the school		
3.School visit	School	<ul> <li>Collect school information according to</li> </ul>	Once a primary	
		Form C1	case is detected	
		<ul> <li>Obtain relevant documents</li> </ul>		
		<ul> <li>Identify contacts</li> </ul>		
		<ul> <li>Organize baseline survey/testing if</li> </ul>		
		possible, at school		
4. Contact	School/ home	Prepare a contact list	Day 1 (Form B1)	
identification		• Explain investigation to individuals (and		
		parent/guardian), obtain informed		
		consent/assent		
		• Arrange baseline testing (at home/specific		
		testing centre if not possible at school)		
		Collect contact baseline information using		
		Form B1		
		<ul> <li>Provide Form B3 and instruct on its use</li> </ul>		
C. Follow-up steps				
5.Contact tracing	School/ home	Conduct daily follow-up of contacts	Days 1–14	
according to			50,5111	
WHO guidance				
6. Management of	Home quarantine	Inform public health authorities	When a contact	
contacts	nome quarantine	<ul> <li>Arrange quarantine, if not already</li> </ul>	becomes	
contacts		occurring, and testing	symptomatic	
		Administer Form A2 if positive	Day 14 (Form A2)	
7.End of the	School/ home			
	School/ nome	Administer Form B2 if the contact did not	Day 14–21 (Form	
follow-up		develop symptoms	<b>B2</b> )	
		<ul> <li>Arrange follow-up testing</li> </ul>	Day 21 (but no	
			later than Day 28)	
D. Final steps				
8. Data analysis	Coordination	Analyse data, results of the laboratory	Every time at the	
	level	evaluations and partial indicators	end of the follow-	
			up in a school	
9. Feedback to	Coordination	<ul> <li>Inform participants of their results</li> </ul>	End of the	
individuals and	level	<ul> <li>Report on school-specific indicators</li> </ul>	investigation in the	
to the school			school	
10.Feedback to	Coordination	<ul> <li>Provide a final report</li> </ul>	End of the	
public health	level		investigation	
authorities				

#### 2.5 Laboratory evaluations

#### 2.5.1 Laboratory analysis

COMMENT: Guidance on laboratory testing is subject to change, depending on the context of the specific evolution of the epidemic.

Guidance on diagnostic testing for SARS-CoV-2 can be found on the WHO website (17).

Ideally, two type of tests will be used in this school-based investigation for case detection: molecular testing and serology.

Laboratory guidance for **molecular testing** for SARS-CoV-2 can be found on the <u>WHO website</u> (17). Several assays that detect SARS-CoV-2 have been recently developed and the protocols or standard operating procedures (SOPs) can also be found on the <u>WHO website</u> (27). The results of these tests are critical to understanding acute infection in participants, so these test results should be prioritized to inform the management of infected individuals and the identification of contacts.

**Serological assays** specific to anti-SARS-CoV-2 antibodies are currently under development/in the process of evaluation.

- The gold standard to determine antibody levels and immunity is a plaque-reduction neutralization test (PRNt), where a monolayer of virus-permissive cells is cultured in the presence of virus and human serum, to determine the amount of growth neutralization the antibodies in the serum specimen can elicit.
- As PRNt is a cumbersome, time-consuming assay, alternative methods like immunofluorescence and, more conveniently and accurately, enzyme immunoassays (e.g. enzyme-linked immunosorbent assays [ELISAs], chemiluminescent immunoassays [CLIAs], etc.) are often used as a proxy to determine serum antibody levels in an individual. Many of the currently available assays target IgG, IgM or both in a single test. Alternatively, tests may target IgA, combine IgA with IgG, or measure total antibodies (IgA, IgG and IgM). Antibodies targeted by the assays may be specific to a viral antigen (for SARS-CoV-2 the most commonly used are: RBD, S1, S2, Spike protein full length or the nucleocapsid protein). The protocols or SOPs will be published on the <u>WHO website</u> (27) once they become available. Cross-reactivity to other coronaviruses may be an issue and should be considered in the interpretation of data.

#### Multiple assays may be required to confirm a seropositive result for SARS-CoV-2.

COMMENT: Countries might want to consider sequencing for genomic and phylogenetic analysis, if sequencing capacity exists at the national level or if a sample of specimens can be can be referred to a reference sequencing laboratory, and also if it is financially feasible. The data may supplement other transmission data to inform estimates of transmission parameters.

#### 2.5.2 Specimen collection

COMMENT: The following is intended to guide minimum specimen collection from confirmed cases and their contacts. It may be useful to collect respiratory specimens from participants at more frequent intervals, to provide more detailed insight into the serial interval.

The baseline respiratory and serum samples (as directed by guidance available at the country level for specimen collection) should be collected from school contacts of the primary cases as soon as possible after their notification. Although currently there are no robust saliva immunoassays available, saliva sampling is easier in children and, at investigation initiation, investigators should consider this approach in light of available oral testing kits. It is important to liaise with the relevant local public health laboratory or the nearest relevant laboratory, to determine which specimens have already been collected for primary cases and whether they are of sufficient quality and quantity for this investigation. New samples should be collected if needed.

**Follow-up respiratory and serum samples** should also be collected from Day 14–21 of the follow-up (if possible). If collection of serum samples is not possible, other options for antibody testing can be collecting **saliva samples** when those tests are validated (see above), or performing rapid diagnostic tests (RDTs) using a finger prick.

Samples should be collected and immediately stored on dry ice until they can be transferred to the participating laboratory for molecular and serologic testing. The investigation team is expected to have these resources when collecting samples. Once in the laboratory, they should be stored **at** – **20** °C or lower (-80 °C) according to storage space available in the laboratory. Serum and saliva samples can continue to be stored at -20 °C or lower (-80 °C) until testing is conducted.

There are **biosafety considerations** to take into account for specimen collection. All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times. Initial processing (before inactivation) of specimens should take place in a validated biological safety cabinet (BSC) or primary containment device. The biosafety guidance for safe collection of sera for suspected COVID-19 patients can be found on the <u>WHO</u> website (28).

#### 2.5.3 Specimen transport

All those involved in collecting and transporting specimens should be trained in safe handling practices and spill decontamination procedures. For details regarding the transport of samples collected and infection control advice, please refer to the case management algorithm and laboratory guidance in the country, or to WHO laboratory guidance, available on the <u>WHO website</u> (17).

For each biological sample collected, the time of collection, the conditions for transportation and the time of arrival at the laboratory will be recorded. Specimens should reach the laboratory as soon as possible after collection. If the specimen is not likely to reach the laboratory within 72 hours, it should be frozen, preferably at -80 °C, and shipped on dry ice. It is, however, important to avoid repeated freezing and thawing of specimens. The storage of respiratory and serum specimens in domestic frost-free freezers should be avoided, owing to their wide temperature fluctuations. Serum should be separated from whole blood and can be stored and shipped at 4 °C or frozen to -20 °C or lower and shipped on dry ice.

Transport of specimens within national borders should comply with applicable national regulations. International transport of specimens should follow applicable international regulations as described in the WHO <u>Guidance on regulations for the transport of infectious substances 2019–2020</u> (29).

#### 2.5.4 Future use of samples

The investigators may wish to store samples and reuse them for future investigations on infectious diseases. If this is the case, the information for the participant and the informed consent/assent forms

must include additional provisions for the storage and future use of samples for future investigations that will be approved by a research ethics committee, in accordance with national regulations. The information for the participant and the informed consent/assent forms also need to anticipate how participants will be informed of the results of any future investigations. Participants will be asked if their samples may be kept for future studies of other infectious pathogens, and will be informed regarding how the samples and data are going to be stored, where they are going to be stored and who is going to be responsible for ensuring the security of that data. Participants have the right to refuse the storage of their sample for future use, in which case their data and samples will be destroyed upon completion of this investigation. This needs to be detailed in the information for the participant and the informed consent/assent forms.

# 2.6 Ethical considerations

**National and local ethical requirements must be followed**. Ethical approval should be sought as per individual country requirements. Ethical requirements will vary by country. In some countries, this investigation may fall under public health surveillance (emergency response) acts and may not require ethical approval from an Institutional Review Board.

Further information on ethical considerations of importance to public health surveillance can be found in key WHO guidance:

- Guidance for managing ethical issues in infectious disease outbreaks. Geneva: World Health Organization; 2016 (<u>https://www.who.int/blueprint/what/research-development/guidance for managing ethical issues.pdf?ua=1</u>) (30).
- WHO guidelines on ethical issues in public health surveillance. Geneva: World Health Organization; 2017 (<u>http://apps.who.int/iris/bitstream/10665/255721/1/9789241512657-eng.pdf?ua=1</u>) (*31*).
- Ethical considerations in developing a public health response to pandemic influenza. Geneva: World Health Organization; 2007 (WHO/CDS/EPR/GIP/2007.2; https://www.who.int/csr/resources/publications/WHO\_CDS\_EPR\_GIP\_2007\_2/en/) (32).

#### 2.6.1 Informed consent and assent

The purpose of the investigation needs to be explained to all individuals willing to participate, before the start of the investigation. For all investigation activities not included in routine public health management, informed consent and assent may be required. This will depend on the country's national ethical requirements:

- Consent for:
  - $\circ \quad \text{adults; and} \quad$
  - children under the legal age of consent (usually 18 years, but will vary from country to country) from a parent or legal guardian.
- Assent from:
  - children and adolescents under the legal age of consent, but who can understand the implications of informed consent and go through the necessary procedures. This is usually children over the age of 12 to 13 years, but this will vary from country to country. A consent form from a parent or legal guardian will also be collected.

All eligible individuals, regardless of whether or not they are well or unwell should be able to participate in the investigation. For individuals who lack the decisional capacity to consent at the time of the investigation, consent/assent by proxy (parent/ guardian/ spouse/ family member) may be considered so as to not unduly exclude individuals from participating in the investigation.

Additional detail in the consent/assent forms may be needed, according to national laws and regulations, if, as mentioned above, the investigation calls for storage and future use of samples.

An appropriately trained member of the investigation team will need to explain to each participant that participation in the investigation is voluntary and that he or she is free to withdraw, without justification, from the investigation at any time without consequences and without affecting professional responsibilities or educational rights. A member of the investigation must also be able to answer any questions any individual willing to participate in the investigation may have related to the procedures of the investigation.

The processes related to withdrawal of a participant need to be described both in the protocol and in the information given to the participant at the time of enrollment. In this description it must be made clear that a participant can withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team. The contact details of one of the members of the investigation need to be provided in the information for the participant. If any participant decides to withdraw from the investigation, the samples collected and data should be discarded, except if the participant indicates that these can be kept for the purpose of conducting the investigation.

# COMMENT: The age of consent and assent for medical procedures may vary by country. Check the requirements of local, regional or national authorities.

Informed consent will seek approval to collect blood, respiratory samples and epidemiological data for the intended purpose of this investigation; that samples may be shipped outside of the country for additional testing; and, in accordance with national regulations, that samples may be used for future public health needs.

COMMENT: Participants or their parent/ guardian/ spouse will be informed about the test results, with an explanation of the interpretation and implications of the test results.

**Informed consent and assent forms templates** for country adaptation to national law and regulation can be found in Appendix B.

#### 2.6.2 Risks and benefits for participants

This investigation poses minimal risk to participants, involving the collection of a respiratory specimen and a small amount of blood and/or saliva.

The direct benefit to the participant is the possibility for early detection of COVID-19, which would allow for appropriate monitoring and treatment for themselves and their close contacts. The primary benefit of the investigation is indirect, in that data collected will help improve and guide efforts to understand transmission of SARS-CoV-2 and and therefore better prevent infections and prevent further spread of the virus.

In terms of treatment of subjects, case management will be facilitated by early detection of the disease and will follow national guidance, but the investigators are not directly involved in clinical management of patients. Processes on how confirmed cases will be referred for medical care, as well as details on provisions of care as part of the investigation will need to be detailed.

The primary benefit of the investigation is to prevent further dissemination of the disease and provide evidence for guiding control measures in this setting.

There will be no incentives while participating in this investigation, but participants will be provided with additional information on means of protection against COVID-19, such as an educational brochure or information sheet.

The time required for data collection, including taking serum and/or saliva and respiratory samples, as well as filling in the questionnaires, will require approximately 30 minutes, initially and at follow up.

In term of plans for dissemination of the results to participants and the community, the results of the blood samples will be disseminated to the participants during the follow-up time, that is, within two weeks after conducting the initial data-collection phase. The results of the investigation can be shared at the end with the participants; this can be done by a small gathering which will take place in the country implementing the investigation. Information at the individual level should be kept anonymous.

#### 2.6.3 Reporting of serious adverse events, including death of a participant

Any serious adverse event, including death, of a participant during the investigation period, needs to be immediately (within 24h) reported to the Principal Investigator and the institution responsible for the investigation. The contact details for reporting serious adverse events needs to be provided to each member of the investigation team.

In accordance with national regulations, any serious adverse event, may also have to be reported to the local ethical review committee, if the adapted protocol was not deemed exempt from local ethical review committee.

#### 2.6.4 Confidentiality and privacy, and data protection

#### National laws and regulations for data protection requirements must be followed.

Participant confidentiality will be maintained throughout the investigation. All subjects who participate in the investigation will be assigned an investigation identification number by the investigation team, for the labelling of questionnaires and clinical specimens. The link of this identification number to individuals will be maintained by the investigation team and the Ministry of Health (or equivalent), separately from the investigation files, and will not be disclosed elsewhere.

Data and specimens will be securely stored nationally. If the data are shared by the implementing organization with WHO or any agency or institution providing support for data analysis, data shared will include only the investigation identification number and not any personably identifiable information. Data sharing outside the country will be managed according to national laws and regulations, as appropriate.

COMMENT: The investigators will need to describe how data and specimens will be securely stored, the duration of storage and the destruction of data and specimens at the end of the duration of storage, in accordance with national laws and regulations. Additional consent forms may need to be developed by the country, according to national laws and regulations, if the investigation calls for storage and future use of samples.

The investigators may decide on potential future use of specimens and the time-frame for destruction of specimens.

COMMENT: The investigators will need to provide more specific information on potential future use of specimens and the time-frame for destruction of specimens, including in the information for the participant and the informed consent/assent forms.

#### 2.6.5 Management and prevention of COVID-19 virus infection

#### Participants

As part of the recruitment process, all eligible participants should be provided information as to how SARS-CoV-2 spread and what measures can be taken to avoid infection. This should include information as to where to seek medical advice related to the investigation, the symptoms associated with SARS-CoV-2 infection and what to do if symptoms develop during the investigation period.

In the context of the current COVID-19 pandemic, WHO recommends the rapid identification of COVID-19 cases and their isolation and management either in a medical facility or an alternative setting, such as the home *(19)*. They should remain isolated (and not resume their activities as part of the investigation) until:

• For symptomatic individuals: 10 days after symptom onset, plus at least 3 additional days without symptoms (including without fever and without respiratory symptoms);

• For asymptomatic individuals: 10 days after positive test for SARS-CoV-2.

WHO recommends that all contacts of confirmed or probable COVID-19 be quarantined in a designated facility or at home for 14 days from their last exposure (18).

COMMENT: The investigators will need to provide specific information on how duty of care will be met for all study participants who are infected, how care will be provided and/or compensated for, if medical care is required.

With respect to the school setting, deciding to close or re-open schools should be guided by a risk-based approach, taking into consideration the epidemiology of COVID-19 at the local level, the capacity of educational institutions to adapt their system to operate safely; the impact of school closures on educational loss, equity, general health and wellbeing of children; and the range of other public health measures being implemented outside school. Decisions on full or partial closure or reopening should be taken at a local administrative level, based on the local level of transmission of SARS-CoV-2 and the local risk assessment, as well as how much the reopening of educational settings might increase transmission in the community. The shutting down educational facilities should only be considered when there are no other alternatives (15).

#### Investigation personnel

All personnel involved in the investigation need to be trained in infection prevention and control procedures (standard contact and droplet precautions, as determined by national or local guidelines These procedures should include proper hand hygiene and the correct use of personal protective equipment (PPE), if necessary, not only to minimize their own risk of infection when in close contact with individuals with SARS-CoV-2 infection, but also to minimize the risk of spread among other participants in the investigation.

Any investigation personnel who develops symptoms consistent with COVID-19 should be immediately isolated and treated as a suspect case of COVID-19 and managed as such. They should remain isolated (and not resume their activities as part of the investigation) until:

- For symptomatic individuals: 10 days after symptom onset, plus at least 3 additional days without symptoms (including without fever and without respiratory symptoms);
- For asymptomatic individuals: 10 days after positive test for SARS-CoV-2.

WHO technical guidance on infection prevention and control specific to COVID-19 can be found on the <u>WHO website</u> (33).

#### Mitigation of stigmatization of participants

There is a possibility of stigmatization of school staff and students involved in the investigation, through participation in the investigation and potentially the results of the investigation, if, for example, particular ethnic minorities, or perhaps those of lower socioeconomic status, are found to have higher rates of infection. The investigators will need to provide specific information on how the risks of stigmatization will be mitigated as part of the implementation of the investigation and the communication of the findings.

#### 2.7 Financing

The investigators will need to detail how the resource costs incurred in data collection, sample collection and laboratory testing will be financed.

# 3. Statistical analyses

#### 3.1 Sample size

The sample size for the investigation will be determined by the number of school contacts of the confirmed COVID-19-infected individual. Every effort should be made to include all contacts of the confirmed COVID-19-infected individual, to maximize the statistical power of the investigation.

Larger studies will permit more robust analysis of potential factors affecting the secondary infection risk, more precise estimation of the asymptomatic proportion, and more detailed characterization of serological responses following infection in younger age groups. The inclusion of casual contacts may not provide much additional information compared to including close contacts, but these contacts can be followed up where resources allow, to help increase the power of the investigation in calculating key transmissibility parameters.

## 3.2 Plan of analyses

School transmission investigation will contribute to responding to the key questions, which can inform public health interventions. Other protocols for investigations for COVID-19 can assist in providing supplementary data to improve estimates of key epidemiological parameters. All WHO investigation protocols for COVID-19 are available on the <u>WHO website</u> (23).

The combination of epidemiological, virological and serological data can provide unparalleled situational awareness of the pandemic in school settings, which will promote a proportionate and targeted public health response.

A descriptive analysis (time, place, person) of the school transmission investigation should provide an insight into the clinical spectrum and course of disease due to COVID-19 infection from individual cases – for example, the number of school contact with symptomatic or asymptomatic confirmed infection, by age and underlying risk factors.

**More advanced analysis**, using the investigation forms/questionnaires and specimens generated, should allow robust estimation of key epidemiological parameters as described in Table 5. The table includes a comments/limitations section, which provides insight into the strengths and weaknesses of this protocol. If sample size allows, those parameters will be stratified by grade, class, close-casual contacts, type of exposure, etc.

# Table 5. Epidemiological parameters that can be estimated during a school transmission investigation to inform investigation primary objectives

to inform investig	acion primary ob		Data source	
			to calculate	
		Definition	the	
Objective	Parameter	Dennition	parameters	Comments, limitations
Estimate	The proportion	The number of	Case and	
Estimate infection rates for overall and secondary SARS- CoV-2 infections; also estimate the secondary clinical attack rate in schools	The proportion of secondary SARS-CoV-2 infections among the contacts of the primary cases	new cases among susceptible contacts exposed to a primary case from 2 days before to 14 days after the date of onset of the primary case divided by the total number of susceptible contacts following exposure to a primary confirmed case	contacts forms (Forms A1 and A2, Forms B1 and B2) Reported symptoms (Form B3) Laboratory form	<ul> <li>to-person infection transmission after the disease has been introduced into a population.</li> <li>Because of the variability in the incubation and infectiousness period, it may be difficult to classify contacts infected as primary or secondary/subsequent cases.</li> <li>School prevention measures can influence the transmissibility of the virus.</li> <li>Past infections should be excluded from the denominator (individuals with IgG detected, recovered cases).</li> <li>Limitations include: <ul> <li>inclusion in the numerator of individuals infected outside the school (over- estimation); false-negative PCR result (under- estimation). Include in the denominator non- susceptible individuals;</li> <li>sensitivity/specificity of the test;</li> <li>timing of specimen collection; and</li> <li>difficulty in classifying primary/secondary cases, leading to misclassification of cases.</li> </ul> </li> </ul>
Estimate the fraction of asymptomatic SARS-CoV-2 infections	The asymptomatic fraction (proportion of cases that are asymptomatic)	The proportion of individuals who reported no symptoms of SARS-CoV-2 infection among individuals who are positive for SARS-CoV-2	Laboratory confirmation and symptoms (Form B3)	<ul> <li>The proportion of asymptomatic individuals may be influenced by:</li> <li>the sensitivity of the test; and</li> <li>the timing of specimen collection.</li> <li>Some COVID-19 symptoms are nonspecific and may be more frequent when other respiratory viruses circulate (e.g. influenza season).</li> </ul>
Describe the	The course of	The identification	Case and	Characteristics noted may only be an
epidemiological	disease (time,	of groups who	contact	early signal; a nested case-control or
characteristics of	person and	are most	forms	retrospective cohort study could be
	, place) in the	vulnerable to	(Forms A1	conducted to evaluate risk
primary and	place in the	vullerable to		

secondary cases of COVID-19	including attack rates by class, grade, students, teacher, activity, etc.	infection (e.g. age groups, gender, occupation, type of contact with case, grade, class, teacher, activity,	Forms B1 and B2)	
		etc.)		
Identify	The risk ratio	The attack rate	Case and	All the limitations indicated for the
potential	for exposure	among exposed	contacts	infection attack rate apply also to this
risk/protective		individuals/attack	forms	objective.
factors		rate among	(Forms A1	
associated with		unexposed	and A2,	
the SARS-CoV-2		individuals	Forms B1	
infection risk			and B2)	
			Laboratory	
			form	

# 4. Reporting of findings

All participants should be informed of their individual results using the contact information collected as part of the investigation. Further, participants should be informed of their molecular testing results as soon as possible. That is, before the end of the investigation.

The schools will also need to receive a report on the findings of the investigation. This should include reporting on the following information, stratified by age-group (e.g. grades, teachers), sex, and relevant time and place (e.g. classes, activities, school bus) characteristics:

- the total number of close and casual school contacts
- the number of cases and number of close (and casual if relevant) school contacts included;
- the number of laboratory-confirmed COVID-19 cases among the close school contacts;
- the number of symptomatic and asymptomatic close school contacts; and
- the number of close contacts with serological evidence of SARS-CoV-2 infection.

Timely dissemination of the results of this investigation is critical to understanding the transmission of SARS-CoV-2, in order to update guidance and inform national and international public health responses and policies for infection prevention and control in the school setting. In this respect, investigators should engage with local communities to communicate the overall findings of the investigation and engage with policy makers and communities of practice.

It is also important to fully document the investigation design, including the definition of close contacts; the approach to ascertainment of primary cases and secondary cases; the duration of follow-up; and the laboratory methods used to ensure that data can be compared across settings.

Ideally, information would be collected in a standardized format according to the questionnaires and tools in this generic protocol, to assist with comparison of results (see forms in Appendix A).

If the data are shared by the implementing organization, with WHO or with any agency or institution providing support for data analysis, data shared will include only the investigation identification number and not any personally identifiable information.

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# 6. Further reading and online courses

- Coronavirus disease (COVID-19) situation reports. Geneva: World Health Organization; 2020 (<u>https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/</u>, accessed 2 July 2020).
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- Coronavirus disease (COVID-19) technical guidance: patient management. Geneva: World Health Organization; 2020 (<u>https://www.who.int/emergencies/diseases/novel-coronavirus-</u> <u>2019/technical-guidance/patient-management</u>, accessed 2 July 2020).

#### Online courses

• There are training resources for COVID-19 available on the WHO online learning platform (<u>https://openwho.org/</u>, accessed 2 July 2020).

# 7. Acknowledgments

This document was developed by: Isabel Bergeri, Richard Pebody, Sonya Olsen, Lorenzo Subissi, Valentina Baltag, Rosamund Lewis, Maria Van Kerkhove (World Health Organization), Camelia Savulescu, Marta Valenciano and Anthony Nardone (Epiconcept, France) and Kristine Macartney (National Centre for Immunisation Research and Surveillance, Australia), with contributions from the following staff and partners: Gianfranco Spiteri, Cornelia Adlhoch and Pasi Penttinen (European Centre for Disease Prevention and Control [ECDC]), Abdi Mahamud and Rebecca Grant (World Health Organization).

The protocol has been revised by bioethicists Michael Parker and Max Smith (University of Oxford). The protocol has also been critically reviewed by Rosalind Eggo (London School of Hygiene and Tropical Medicine), Sheri Kardooni (Prevent Epidemics), Ana Isabel Bento (Indiana University, USA), and Eugenio Beltran (New York University College of Dentistry, USA).

This generic protocol built also on experience and protocols developed through the WHO Pandemic Influenza Special Investigations and Studies work. It is based on the *Closed setting transmission investigation protocol for pandemic influenza A(HxNy),* draft version 2, October 2019, and *The First Few X cases and contacts (FFX) investigation protocol for pandemic influenza A(HxNy),* draft version 7, January 2020 (*34*).

This generic protocol development benefited from the work of the Consortium for the Standardization of Influenza Seroepidemiology (CONSISE). CONSISE is a global partnership aiming to develop influenza investigation protocols and standardize seroepidemiology to inform public health policy for pandemic, zoonotic and seasonal influenza. This international partnership was created out of a need, identified during the 2009 H1N1 pandemic, for better (standardized, validated) seroepidemiological data to estimate infection attack rates and the severity of the pandemic virus and to inform policy decisions.

The members of the WHO Expert Working Group on Pandemic Influenza Special Investigations and Studies substantively supported the development of the pandemic influenza version of the early investigation protocols, by providing strategic direction and direct inputs on the drafts. These include (in alphabetical order): Silke Buda (RK Institute, Germany), Cheryl Cohen (Ministry of Health, South Africa), Ben Cowling (Hong Kong University), Jeffery Cutter (Ministry of Health, Singapore), Rodrigo Fasce (NIC, Chile), Gail Garson (GOARN Operational Support Team – Chair of Research Subgroup, United Kingdom of Great Britain and Northern Ireland), Arunkumar Govindakarnavar (Manipal Institute of Virology, Manipal Academy of Higher Education, India), Jean-Michel Heraud (Institut Pasteur de Madagascar, Madagascar), Peter Horby (ISARIC, United Kingdom of Great Britain and Northern Ireland), Sue Huang (Institute of Environmental Science and Research, New Zealand), Bryan Kim (GOARN Operational Support Team, Switzerland), Vernon Lee (Ministry of Health, Singapore), Adrian Marcato (University of Melbourne, Australia), Jodie McVernon (Peter Doherty Institute, Australia), Richard Pebody (Public Health England, United Kingdom of Great Britain and Northern Ireland), Melissa Rolf (US Centers for Disease Control and Prevention, United States of America), Hassan Zaraket (American University of Beirut, Lebanon) and Lei Zhou (Chinese Center for Disease Control and Prevention, China).

The recertification verification code for this document is 857675.

# Appendix A: Questionnaires and guidance

# Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)

#### FOR CASES

- Form A1: Case initial reporting form for confirmed COVID-19 cases (Day 1)
- Form A2: Case follow-up reporting form for confirmed COVID-19 cases (Day 14)

#### FOR CONTACTS

- Form B1: Contact initial reporting form for close/casual contacts of confirmed COVID-19 cases (Day 1)
- Form B2: Contact follow-up reporting form for close/casual contacts of confirmed COVID-19 cases (Day 14-21)
- Form B3: Symptom diary for close/casual contacts of confirmed COVID-19 cases

#### FOR SCHOOLS

• Form C1: School reporting form

#### 1. For cases

# Form A1: Case initial reporting form – for confirmed COVID-19 cases (Day 1)

#### Unique Primary Case ID/Cluster number (if applicable):

Informed/assent consent	
Informed consent signed	□ Yes □ No □ Unknown

# 1. Current status Alive Dead Unknown/lost to follow-up 2. Further case classification Primary Secondary Subsequent (note the generation if possible)

3. Data collector information		
Name of data collector		
Data collector institution		
Data collector telephone number		
Data collector email		
Form completion date (dd/mm/yyyy)		

4. Interview respondent information (if the person providing the information is not the patient) COMMENT: For children, this information should be collected for parents, legal tutor/guardian.			
First name			
Family name			
Sex	🗆 Male 🗆 Female 🗆 Not known		
Date of birth (dd/mm/yyyy)	/ □ Unknown		
Relationship to patient			
Respondent address			
Telephone (mobile) number			
Email			
Preferred mode of contact	🗆 Mobile 🗆 Work 🗆 Home 🗆 Email		

5. Patient identifier information			
COMMENT: No information on children's contact details	COMMENT: No information on children's contact details (telephone number, address or email) should be		
collected; this information should only be provided for t	heir parents, legal tutor/guardian (see section 4).		
First name			
Family name			
Sex	🗆 Male 🗆 Female 🗆 Not known		
Date of birth (dd/mm/yyyy)	/		
	🗆 Unknown		
Telephone (mobile) number			
Email			
Address			
National social number/identifier (if applicable)			

Country of residence	
Nationality	
Ethnicity (optional)	
Responsible health centre	
Nursery/school/college (if relevant)	
Class/Grade	
Patient occupation (specify location/facility)	<ul> <li>Staff (teacher)</li> <li>Staff (administrative)</li> <li>Staff (ancillary)</li> <li>Student</li> <li>Other, specify:</li> </ul>
For teachers (delete as appropriate)	Teach one class only/Teach more than one class

6. Health-care centre/treating physician's details	
Name of health-care centre	
Name of treating physician	
Telephone number	
Email	
Address	

7a. Patient symptoms (from onset of symptoms)		
Patient presented symptoms?	🗆 Yes 🗆 No symptoms 🗆 Unknown	
Date of first symptom onset (dd/mm/yyyy)		
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, specify maximum temperature: °C	
7b. Respiratory symptoms		
Sore throat	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy)://	
Runny nose	🗆 Yes 🗆 No 🗆 Unknown	
Cough	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy)://	
Shortness of breath	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy)://	
7c. Other symptoms		
Chills	🗆 Yes 🗆 No 🗆 Unknown	
Vomiting	🗆 Yes 🗆 No 🗆 Unknown	
Nausea	🗆 Yes 🗆 No 🗆 Unknown	
Diarrhoea	🗆 Yes 🗆 No 🗆 Unknown	
Headache	🗆 Yes 🗆 No 🗆 Unknown	
Rash	🗆 Yes 🗆 No 🗆 Unknown	
Conjunctivitis	🗆 Yes 🗆 No 🗆 Unknown	
Muscle aches	🗆 Yes 🗆 No 🗆 Unknown	
Joint ache	🗆 Yes 🗆 No 🗆 Unknown	

Loss of appatito	
Loss of appetite	🗆 Yes 🗆 No 🗆 Unknown
Loss of smell (anosmia) or taste (ageusia)	🗆 Yes 🗆 No 🗆 Unknown
Nose bleed	🗆 Yes 🗆 No 🗆 Unknown
Fatigue	🗆 Yes 🗆 No 🗆 Unknown
Seizures	🗆 Yes 🗆 No 🗆 Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify
Other symptoms	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify:

8. Patient symptoms: complications	
Hospitalization	🗆 Yes 🗆 No 🗆 Unknown
Date of first hospitalization (dd/mm/yyyy)	
	🗆 Unknown
ICU (intensive care unit) admission	🗆 Yes 🗆 No 🗆 Unknown
Date of ICU admission (dd/mm/yyyy)	
	🗆 Unknown
Date of discharge from ICU (dd/mm/yyyy)	//
	🗆 Unknown 🗆 Not applicable (na)
Mechanical ventilation	🗆 Yes 🗆 No 🗆 Unknown
Dates of mechanical ventilation (dd/mm/yyyy)	Start://
	Stop://
	🗆 Unknown 🗆 na
Length of ventilation (days)	
Acute respiratory distress syndrome (ARDS)	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Acute renal failure	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Cardiac failure	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Consumptive coagulopathy	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Multi-system inflammatory syndrome	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Pneumonia by chest X-ray	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date started (dd/mm/yyyy)//
Other complications	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify:
Hypotension requiring vasopressors	🗆 Yes 🗆 No 🗆 Unknown
Extracorporeal membrane oxygenation (EMO) required	🗆 Yes 🗆 No 🗆 Unknown
Date of discharge from hospital (if applicable)	
(dd/mm/yyyy)	_
Outcome	🗆 Alive 🗆 Dead 🗆 na 🗆 Unknown
Outcome current as of date (dd/mm/yyyy)	
	🗆 Unknown 🗆 na

9. Patient pre-existing condition(s)	
Pregnancy	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify trimester:
	First Second Third Unknown
Obesity	🗆 Yes 🗆 No 🗆 Unknown
Cancer	🗆 Yes 🗆 No 🗆 Unknown
Diabetes	🗆 Yes 🗆 No 🗆 Unknown
HIV/other immune deficiency	🗆 Yes 🗆 No 🗆 Unknown
Heart disease	🗆 Yes 🗆 No 🗆 Unknown
Asthma (requiring medication)	🗆 Yes 🗆 No 🗆 Unknown
Chronic lung disease (non-asthma)	🗆 Yes 🗆 No 🗆 Unknown
Chronic liver disease	🗆 Yes 🗆 No 🗆 Unknown
Chronic haematological disorder	🗆 Yes 🗆 No 🗆 Unknown
Chronic kidney disease	🗆 Yes 🗆 No 🗆 Unknown
Chronic neurological impairment/disease	🗆 Yes 🗆 No 🗆 Unknown
Organ or bone marrow recipient	🗆 Yes 🗆 No 🗆 Unknown
Other pre-existing condition(s)	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify:

10. Human exposures in the days before symptom onset	(14 days before symptom onset)
Is the source of the infection known?	□ Yes □ No □ Possible □ Unknown If Yes, specify
Has the patient travelled within the last 14 days domestically?	□ Yes □ No □ Unknown
Has the patient travelled within the last 14 days internationally?	🗆 Yes 🗆 No 🗆 Unknown
In the past 14 days, has the patient had contact with anyone with suspected or confirmed COVID-19 infection?	<ul> <li>Yes <ul> <li>No <ul> <li>Unknown</li> <li>If Yes, dates of last contact (dd/mm/yyyy):</li> <li>//</li> </ul> </li> </ul></li></ul>
Has the patient attended a community event(s) (especially high-risk events like a closed-setting crowded gathering: religious event, wedding, party, dance, concert, banquet, festival, sports event, funeral or other	□ Yes □ No □ Unknown If Yes, specify the type of event:
event) in the past 14 days?	If Yes, date(s) of the event(s) (dd/mm/yyyy):
Location of potential exposure in the past 14 days	<ul> <li>Home          <ul> <li>Hospital</li> <li>Birthday party</li> <li>Religious event</li> <li>Tour group</li> <li>School</li> <li>Unknown</li> <li>Other, specify:</li> </ul> </li> </ul>

11. Exposures in school before symptom onset (in the past 14 days for secondary/subsequent cases)

The patient had close contact with the primary case	🗆 Yes 🗆 No 🗆 Unknown
(within 1 metre)	If Yes, how many times (total)?
The patient had close contact with the primary case	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, for how long:
	□ <5 minutes
	□ 5–15 minutes
	□ >15 minutes
If no close contact for both close contact definitions (time >15 min and distance), the patient had a casual contact with the primary case	□ Yes □ No □ Unknown. If Yes, please describe the type of contact
If Yes for any of the close contact definitions, please collect additional information	
Transport to school with a primary case	Foot Bike Car School transport Other
	If Yes, how many times (total)?
	If Yes, duration of journey
Class with a primary case	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, how many times (total) and length of time
Group activities in school with a primary case	🗆 Sport
	🗆 Theatre
	🗆 Canteen
	Assemblies (daily or weekly)
	🗆 Other
	For each activity, note how many times (total) and
	length of time
Other type of close contact	Please specify

12. Protective measures taken at school during the period of infectiousness		
COMMENT: This section provides only examples of exposures at school, and should be adapted by the		
investigation teams according to the organization and lo	cal recommendation	
Did the patient wear a mask at school?	Yes Do Not recommended Duknown	
If the patient was wearing a mask at school, what type:	Respirator (FFP2 or N95 mask or equivalent)	
	Surgical/medical mask	
	Fabric mask	
	Face shield	
	Other, specify:	
How often did the patient wear the mask at school?	🗆 Always	
	Most of the time	
	Occasionally	
	Rarely	
Did the patient perform hand hygiene at school?	Always, as recommended	
	Most of the time	
	Occasionally	
	Rarely	
	If Yes:	
	Alcohol-based hand rub	
	Soap and water	
	Water	

Mosthe notions properties and for any discribed and the second state	
Was the patient present for any droplet/aerosolizing activities (singing, playing wind instruments, sports,	🗆 Yes 🗆 No 🗆 Unknown
etc.)?	If Yes, describe the activity:
	If Yes, did you wear protection?
	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, what type?
	Tick all that apply:
	Respirator (FFP2 or N95 mask or equivalent)
	Medical/surgical mask
	Fabric mask
	Face shield
	Other, specify:
Did the patient have direct contact with materials/objects of other persons at school: children/staff?	□ Yes □ No □ Unknown
Devery's metericle, never al holen since elether	
Person's materials: personal belongings, clothes, teaching material	
-	Tick all that apply:
If Yes, which materials?	Tick all that apply:
	Other personal items     Tracking metarial
	Teaching material     Other encoder
	□ Other, specify:
If Yes, did the patient perform hand hygiene after	Always, as recommended
contact with these materials?	Most of the time
	Occasionally
	🗆 Rarely
	If Yes:
	Alcohol-based hand rub
	Soap and water
	🗆 Water
Other type of contact at school when infectious, please	
describe	

complete a ne	w line for each spe	cimen collected an	d each type of test d	one:		1	
Laboratory	Date sample	Date sample	Type of sample	Type of test	Result	Result date	Specimens shipped
identification	collected	received				(dd/mm/yyyy)	to other laboratory
number	(dd/mm/yyyy)	(dd/mm/yyyy)					for confirmation
	//	//	<ul> <li>Nasal swab</li> <li>Throat swab</li> <li>Nasopharyngeal swab</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	<ul> <li>PCR</li> <li>Whole genome sequencing</li> <li>Partial genome sequencing</li> <li>Other, specify</li> </ul>	<ul> <li>POSITIVE for SARS-CoV-2</li> <li>NEGATIVE for SARS-CoV-2</li> <li>POSITIVE for other pathogens</li> <li>Please specify which pathogens:</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>//</li> <li>If Yes, name of the</li> <li>laboratory:</li> <li>No</li> </ul>

Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result (SARS-CoV-2 antibody titres)	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	//	//	<ul> <li>Serum</li> <li>Saliva</li> <li>Other,</li> <li>specify:</li> </ul>	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.) and the brand:	<ul> <li>POSITIVE</li> <li>If positive, specify type</li> <li>and titre of antibody</li> <li>detected (Total, IgM, IgA,</li> <li>IgG)</li> <li>NEGATIVE</li> <li>INCONCLUSIVE</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>//</li> <li>If Yes, name of the</li> <li>laboratory:</li> <li>No</li> </ul>

14. Status of form completion	
Form completed	Yes      No or partially
	If Ne or portiolly, recent
	If No or partially, reason:
	Missed
	Not attempted
	Not performed
	Refusal
	□ Other, specify:

*Form A2: Case follow-up reporting form – for confirmed COVID-19 cases (Day 14)* 

COMMENT: Information in this form may already have been completed in the *Case initial reporting form – for confirmed COVID-19 cases (Day 1)* (Form A1). It is therefore not necessary to repeat any data in these sections that have already been completed.

#### Unique Case ID/Cluster number (if applicable):

1. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	

2. Interview respondent information (if different from initial interview) COMMENT: For children, this information should be collected for parents, legal tutor/guardian.		
First name		
Family name		
Sex	Male - Female - Not known	
Date of birth (dd/mm/yyyy)	/ □ Unknown	
Relationship to patient		
Respondent address		
Telephone (mobile) number		
Email		
Preferred mode of contact	Mobile      Work      Home      Email	

3. Outcome/status		
Status	Recovered, if Yes specify date symptoms resolved	
	(dd/mm/yyyy)	
	🗆 Still ill	
	Dead, if Yes, specify date of death (dd/mm/yyyy):	
	/	
	Unknown/lost to follow-up	
Hospitalization ever required?	🗆 Yes 🗆 No 🗆 Unknown	
(NB. If the information below is not currently available, please leave blank and send through an update as soc		
as results are available)		
If dead, contribution of COVID-19 to death:	Underlying/primary	
	Contributing/secondary	
	No contribution to death	
	🗆 Unknown	
If dead, was a postmortem performed?	🗆 Yes 🗆 No 🗆 Unknown	

If dead, results of postmortem's report where available:	
If dead, cause of death on Death certificate	
(specify)	

4a. Patient symptoms during the entirety of	
Maximum temperature (specify)	°C □ Not applicable (na)
4b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown
	If Yes, date (dd/mm/yyyy)//
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown
	If Yes, date (dd/mm/yyyy)//
Shortness of breath	□ Yes □ No □ Unknown
	If Yes, date (dd/mm/yyyy)//
4c. Other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Loss of smell (anosmia) or taste (ageusia)	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	□ Yes □ No □ Unknown
	If Yes, specify
Other symptoms	□ Yes □ No □ Unknown
	If Yes, specify:

5. Patient symptoms: complications	
Hospitalization	🗆 Yes 🗆 No 🗆 Unknown
Date of first hospitalization (dd/mm/yyyy)	// □ Unknown
ICU (intensive care unit) admission	🗆 Yes 🗆 No 🗆 Unknown
ICU admission	

	🗆 Unknown
Date of discharge from ICU (dd/mm/yyyy)	// □ Unknown □ na
Mechanical ventilation	🗆 Yes 🗆 No 🗆 Unknown
Dates of mechanical ventilation (dd/mm/yyyy)	Start//           Stop//           □ Unknown □ na
Length of ventilation (days)	
Acute respiratory distress syndrome (ARDS)	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Acute renal failure	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Cardiac failure	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Consumptive coagulopathy	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Multi-system inflammatory syndrome	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Pneumonia by chest X-ray	□ Yes □ No □ Unknown If Yes, date started (dd/mm/yyyy)//
Other complications	□ Yes □ No □ Unknown If Yes, specify:
Hypotension requiring vasopressors	□ Yes □ No □ Unknown
Extracorporeal membrane oxygenation (EMO) required	□ Yes □ No □ Unknown

6. Patient pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If yes, specify trimester:
	□ First □ Second □ Third □ Unknown

7. Secondary bacterial infection				
Complete a new line for each specimen collected and each type of test done:				
Date of sample (dd/mm/yyyy)	Type of sample	Positive results		
//	🗆 Sputum	🗆 Haemophilus influenza		
	Endotracheal aspirate	🗆 MRSA		
	Pleural fluid	Staphylococcus aureus		
	□ CSF	Streptococcus pneumoniae		
	□ Blood	🗆 E. coli		
	🗆 Urine	Other organism, please specify:		
	Faeces			
	Other, please specify:			

Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	//	//	<ul> <li>Nasal swab</li> <li>Throat swab</li> <li>Nasopharyngeal</li> <li>swab</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	<ul> <li>PCR</li> <li>Whole genome sequencing</li> <li>Partial genome sequencing</li> <li>Other, specify</li> </ul>	<ul> <li>POSITIVE for SARS-CoV-2</li> <li>NEGATIVE for SARS-CoV-2</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>//</li> <li>If Yes, name of the</li> <li>laboratory:</li> </ul>
					<ul> <li>POSITIVE for other pathogens</li> <li>Please specify which pathogens:</li> </ul>		□ No

Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result (SARS-CoV-2 antibody titres)	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	//	//	<ul> <li>Serum</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	Specify type (ELISA / IFA IgM/ IgG, neutralization assay, etc.) and brand:	<ul> <li>POSITIVE</li> <li>If positive, specify type and titre of antibody detected (Total, IgM, IgA, IgG)</li> <li>NEGATIVE</li> <li>INCONCLUSIVE</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>//</li> <li>If Yes, name of the laboratory:</li> <li>No</li> </ul>

9. Status of form completion	
Form completed	□ Yes □ No or partially
	If No or partially, reason: <ul> <li>Missed</li> <li>Not attempted</li> <li>Not performed</li> <li>Refusal</li> <li>Other, specify:</li> </ul>

## Form B1: Contact initial reporting form – for close/casual contacts of confirmed cases (Day 1)

## 2. For contacts

*Form B1: Contact initial reporting form – for close/casual contacts of confirmed COVID-19 cases (Day 1)* 

#### Name of confirmed case

#### Confirmed Case ID/Cluster number (if applicable):

#### Contact ID Number (C...):

Note: Contact ID numbers should be issued at the time of completion of Form A1.

Informed/assent consent	
Informed consent signed	🗆 Yes 🗆 No 🗆 Unknown

1. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	

	ersons providing the information is not the contact) ould be collected for parents, legal tutor/guardian.
First name	
Family name	
Sex	🗆 Male 🗆 Female 🗆 Not known
Date of birth (dd/mm/yyyy)	// □ Unknown
Relationship to patient	
Respondent address	
Telephone (mobile) number	
Email:	
Preferred mode of contact	🗆 Mobile 🗆 Work 🗆 Home 🗆 Email

3. Contact details (details of the contact)		
COMMENT: No information on children's contact details (telephone number, address or email) should be		
collected; this information should only be provided for their parents, legal tutor/guardian (see section 2).		
First name		
Family name		
Sex	🗆 Male 🗆 Female 🗆 Not known	
Date of birth (dd/mm/yyyy)		
	🗆 Unknown	

Relationship to case	
Telephone (mobile) number	
Email	
Address	
Preferred mode of contact	🗆 Mobile 🗆 Work 🗆 Home 🗆 Email
National social number/identifier (optional)	
Nationality	
Ethnicity (optional)	
Country of residence	
Nursery/school/college (if relevant)	
Class/Grade	
Patient occupation (specify location/facility)	□ Staff (teacher)
	Staff (administrative)
	Staff (ancillary)
	Student
	Other (specify)
For teachers (delete as appropriate)	Teach one class only/Teach more than one class

4. General exposure information	
Has the contact travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (dd/mm/yyyy): /to// Regions visited: Cities visited:
Has the contact travelled within the last 14 days internationally?	<ul> <li>Yes Do Duknown</li> <li>If Yes, dates of travel (dd/mm/yyyy):</li> <li>/ to//</li> <li>Countries visited:</li> <li>Cities visited:</li> </ul>
Has the contact attended a community event(s) (especially high-risk events like a closed-setting crowded gathering: religious event, wedding, party, dance, concert, banquet, festival, sports event, funeral or other event) in the past 14 days?	□ Yes □ No □ Unknown If Yes, specify the type of event: If Yes, date(s) of the event(s) (dd/mm/yyyy):

In the past 14 days, has the contact had contact with anyone with suspected or confirmed COVID-19 infection outside school?	□ Yes □ No □ Unknown If Yes, dates of last contact (dd/mm/yyyy): //
School exposure with whom?	<ul> <li>Staff (teacher in the primary case class)</li> <li>Staff (administrative)</li> <li>Staff (ancillary)</li> <li>Student in the same class</li> <li>Other (specify)</li> </ul>

5. Exposure information (specify during the interview the period of infectiousness of the primary case)		
Type of contact	<ul> <li>Close</li> <li>Casual</li> <li>Other, specify:</li> </ul>	
Specify characteristics of contact with the confirmed case from first	Date (dd/mm/yyyy)	
contact, while the primary case was symptomatic	Duration	(minutes)
(Add as many dates as required)	Setting	<ul> <li>Classroom</li> <li>Activity</li> <li>Canteen</li> <li>Outdoor</li> <li>Other, specify:</li> </ul>
Specify characteristics of contact with the confirmed case from first	Date (dd/mm/yyyy)	
contact, while the primary case was asymptomatic	Duration	(minutes)
(Add as many dates as required)	Setting	<ul> <li>Classroom</li> <li>Activity</li> <li>Canteen</li> <li>Outdoor</li> <li>Other, specify:</li> </ul>

5a. Symptoms in contact	
Has the contact experienced any respiratory	□ Yes
symptoms (sore throat, runny nose, cough,	□ No
shortness of breath) in the period from 14 days	
before symptom onset in the confirmed case until	
the present?	
Has the contact experienced any respiratory	□ Yes
symptoms (sore throat, runny nose, cough,	□ No
shortness of breath) in the period up to 14 days	
after the last contact or until the present date,	
whichever is the earlier?	

Currently ill at the date of interview (dd/mm/yyyy):	🗆 Yes 🗆 No
Date (dd/mm/yyyy) and time of first symptom onset	
	□ am □ pm
Fever (>38 °C) or history of fever	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date//
Maximum temperature	°C 🗆 Not applicable (na)
5b. Respiratory symptoms	
Sore throat	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, date//
Runny nose	🗆 Yes 🗆 No 🗆 Unknown
Cough	🗆 Yes 🗆 No 🗆 Unknown
-	If Yes, date//
Shortness of breath	□ Yes □ No □ Unknown
	If Yes, date//
5c. other symptoms	
Chills	🗆 Yes 🗆 No 🗆 Unknown
Vomiting	🗆 Yes 🗆 No 🗆 Unknown
Nausea	🗆 Yes 🗆 No 🗆 Unknown
Diarrhoea	🗆 Yes 🗆 No 🗆 Unknown
Headache	🗆 Yes 🗆 No 🗆 Unknown
Rash	🗆 Yes 🗆 No 🗆 Unknown
Conjunctivitis	🗆 Yes 🗆 No 🗆 Unknown
Muscle aches	🗆 Yes 🗆 No 🗆 Unknown
Joint ache	🗆 Yes 🗆 No 🗆 Unknown
Loss of appetite	🗆 Yes 🗆 No 🗆 Unknown
Loss of smell (anosmia) or taste (ageusia)	🗆 Yes 🗆 No 🗆 Unknown
Nose bleed	🗆 Yes 🗆 No 🗆 Unknown
Fatigue	🗆 Yes 🗆 No 🗆 Unknown
Seizures	🗆 Yes 🗆 No 🗆 Unknown
Altered consciousness	🗆 Yes 🗆 No 🗆 Unknown
Other neurological signs	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify
Other symptoms	□ Yes □ No □ Unknown
	If Yes, specify:

6. Outcome/status of contact (only complete if contact has been ill or is currently ill)		
Status	<ul> <li>Recovered, if Yes, specify date symptoms resolved (dd/mm/yyyy)</li> <li>//</li> <li>Still ill</li> <li>Dead, if Yes, specify date of death (dd/mm/yyyy)</li> <li>//</li> <li>Unknown/lost to follow-up</li> </ul>	

# Form B1: Contact initial reporting form – for close/casual contacts of confirmed cases (Day 1)

Hospitalization ever required?	□ Yes □ No □ Unknown If Yes, date of hospitalization and date of discharge (dd/mm/yyyy) / to/
(NB. If the information below is not current as results are available)	ly available, please leave blank and send through an update as soon
If dead, contribution of COVID-19 to death:	<ul> <li>Underlying/primary</li> <li>Contributing/secondary</li> <li>No contribution to death</li> <li>Unknown</li> </ul>
If dead, was a postmortem performed?	🗆 Yes 🗆 No 🗆 Unknown
If dead, results of postmortem's report where available:	
If dead, cause of death on Death certificate (specify)	

7. Contact pre-existing condition(s)		
Pregnancy	🗆 Yes 🗆 No 🗆 Unknown	
	If Yes, specify trimester:	
	First Second Third Unknown	
Obesity	🗆 Yes 🗆 No 🗆 Unknown	
Cancer	🗆 Yes 🗆 No 🗆 Unknown	
Diabetes	🗆 Yes 🗆 No 🗆 Unknown	
HIV/other immune deficiency	🗆 Yes 🗆 No 🗆 Unknown	
Heart disease	🗆 Yes 🗆 No 🗆 Unknown	
Asthma requiring medication	🗆 Yes 🗆 No 🗆 Unknown	
Chronic lung disease (non-asthma)	🗆 Yes 🗆 No 🗆 Unknown	
Chronic liver disease	🗆 Yes 🗆 No 🗆 Unknown	
Chronic haematological disorder	🗆 Yes 🗆 No 🗆 Unknown	
Chronic kidney disease	🗆 Yes 🗆 No 🗆 Unknown	
Chronic neurological impairment/disease	🗆 Yes 🗆 No 🗆 Unknown	
Organ or bone marrow recipient	🗆 Yes 🗆 No 🗆 Unknown	
Other pre-existing condition(s)	🗆 Yes 🗆 No 🗆 Unknown	
	If Yes, specify:	
Comments if appropriate		

8. Protective factor(s) at the moment of contact with a confirmed case COMMENT: This section provides only examples of exposures at school, and should be adapted by the		
investigation teams according to the organization and local recommendation.		
Did the contact wear a mask at school?	Yes I No I Not recommended	
	🗆 Unknown	
If the contact was wearing a mask at school, what type:	Respirator (FFP2 or N95 mask or	
	equivalent)	
	Surgical/medical mask	
	Fabric mask	
	Face shield	
	Other, specify:	

How often did the contact wear the mask at school?	Always
	□ Most of the time
	□ Rarely
Did the contact perform hand hygiene <b>before</b> contact with the case?	□ Always, as recommended
	□ Most of the time
	□ Occasionally
	□ Rarely
	If Yes:
	□ Alcohol-based hand rub
	□ Soap and water
	□ Water
Did the contact perform hand hygiene <b>after</b> contact with the case?	□ Always, as recommended
	□ Most of the time
	□ Rarely
	If Yes:
	□ Alcohol-based hand rub
	□ Soap and water
	□ Water
Was the contact present for any droplet/aerosolizing activities	□ Yes □ No □ Unknown
(singing, playing wind instruments, sports, etc.) of the case?	
	If Yes, describe the activity:
	If Yes, did you wear protection?
	$\Box$ Yes $\Box$ No $\Box$ Unknown
	If Yes, what type?
	Tick all that apply:
	□ Respirator (FFP2 or N95 mask or
	equivalent)
	Surgical/medical mask
	□ Fabric mask
	□ Face shield
	□ Other, specify:
Has the contact had direct contact with the case's materials/objects	🗆 Yes 🗆 No 🗆 Unknown
when the case was infectious?	
Patient's materials: personal belongings, clothes, teaching material	
If Yes, which materials?	Tick all that apply:
	□ Clothes
	Other personal items
	Teaching material used by the case
	□ Other:
If Yes, how many times when the case was infectious (total)?	

If Yes, did the contact perform hand hygiene after contact with the	Always, as recommended
cases's materials?	Most of the time
	Occasionally
	Rarely
	If Yes:
	Alcohol-based hand rub
	Soap and water
	🗆 Water
Has the contact had direct contact with the surfaces around the	🗆 Yes 🗆 No 🗆 Unknown
case?	
If Yes, which surfaces?	Tick all that apply:
	🗆 Desk
	🗆 Bathroom
	🗆 Corridor
	Table at canteen
	🗆 Other:
If Yes, how many times when the case was infectious (total)?	
Other type of contact, please describe	

Complete a new line for each specimen collected and each type of test done:								
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation	
	//	//	<ul> <li>Nasal swab</li> <li>Throat swab</li> <li>Nasopharyngeal</li> <li>swab</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	<ul> <li>PCR</li> <li>Whole genome sequencing</li> <li>Partial genome sequencing</li> <li>Other, specify</li> </ul>	<ul> <li>POSITIVE for SARS-CoV-2</li> <li>NEGATIVE for SARS-CoV-2</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>/</li> <li>If Yes, name of the laboratory:</li> </ul>	
					<ul> <li>POSITIVE for other pathogens</li> <li>Please specify which pathogens:</li> </ul>		□ No	

Complete a ne	w line for each spe	cimen collected an	d each type of test	done:			
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result (SARS-CoV-2 antibody titres)	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	//	//	<ul> <li>Serum</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.) and brand:	<ul> <li>POSITIVE</li> <li>If positive, specify type</li> <li>and titre of antibody</li> <li>detected (Total, IgM, IgA,</li> <li>IgG)</li> <li>NEGATIVE</li> </ul>	/	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>/</li> <li>If Yes, name of the laboratory:</li> <li>No</li> </ul>

10. Status of form comple	tion	
Form completed	□ Yes □ No or partially	
	If No or partially, reason: <ul> <li>Missed</li> <li>Not attempted</li> <li>Not performed</li> <li>Refusal</li> <li>Other, specify:</li> </ul>	

Form B2: Contact follow-up reporting form – for close/casual contacts of confirmed cases (Day 14–21)

*Form B2: Contact follow-up reporting form – for close/casual contacts of confirmed COVID-19 cases (Day 14–21)* 

COMMENT: Information in this form may already have been completed in the *Contact initial reporting form* (Form B1). It is therefore not necessary to repeat any data in these sections that have already been completed.

#### Name of confirmed case:

#### Unique Case ID/Cluster number (if applicable):

Contact ID number (C...):

1. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	

2. Interview respondent information (if the person providing the information is not the contact)							
COMMENT: For children, this information should be collected for parents, legal tutor/guardian.							
First name							
Family name							
Sex	🗆 Male 🗆 Female 🗆 Not known						
Date of birth (dd/mm/yyyy)							
Relationship to patient							
Respondent address							
Telephone (mobile) number							

3. Exposure information		
Type of contact	Close Close	
	□ Other, specify:	
Specify characteristics of contact with the confirmed case from first	Date (dd/mm/yyyy)	
contact, while the primary case was <b>symptomatic</b>	Duration	(minutes)
(Add as many dates as required)	Setting	Classroom
		Activity
		Canteen
		Outdoor
		Other, specify:

Specify characteristics of contact with the confirmed case from first	Date (dd/mm/yyyy)	
contact, while the primary case was <b>asymptomatic</b>	Duration	(minutes)
(Add as many dates as required)	Setting	<ul> <li>Classroom</li> <li>Activity</li> <li>Canteen</li> <li>Outdoor</li> <li>Other, specify:</li> </ul>

4a. Symptoms in contact	
Has the contact experienced any respiratory symptoms	🗆 Yes 🗆 No
(sore throat, runny nose, cough, shortness of breath) in	
the period from 14 days <b><u>before</u></b> symptom onset in the	
confirmed case until the present?	
Has the contact experienced any respiratory symptoms	🗆 Yes 🗆 No
(sore throat, runny nose, cough, shortness of breath) in	
the period up to 14 days <u>after</u> the last contact or until	
the present date, whichever is the earlier?	
Currently ill at the interview date//	🗆 Yes 🗆 No
Please only complete following section if contact has de	emonstrated symptoms since last follow-up:
Date (dd/mm/yyyy) and time of first symptom onset	//
	🗆 am 🗆 pm
Fever (>38 °C) or history of fever	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, dates (dd/mm/yyyy to dd/mm/yyyy)
	/to/
Maximum temperature	°C 🗆 Not applicable (na)
4b. Respiratory symptoms	
Sore throat	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, dates (dd/mm/yyyy to dd/mm/yyyy)
	/to/
Puppy poso	🗆 Yes 🗆 No 🗆 Unknown
Runny nose	
Cough	□ Yes □ No □ Unknown
	If Yes, dates (dd/mm/yyyy to dd/mm/yyyy)
	/to/
Shortness of breath	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, dates (dd/mm/yyyy to dd/mm/yyyy)
	/to/

Form B2: Contact follow-up reporting form – for close/casual contacts of confirmed cases (Day 14–21)

4c. other symptoms	
Chills	🗆 Yes 🗆 No 🗆 Unknown
Vomiting	🗆 Yes 🗆 No 🗆 Unknown
Nausea	🗆 Yes 🗆 No 🗆 Unknown
Diarrhoea	🗆 Yes 🗆 No 🗆 Unknown
Headache	🗆 Yes 🗆 No 🗆 Unknown
Rash	🗆 Yes 🗆 No 🗆 Unknown
Conjunctivitis	🗆 Yes 🗆 No 🗆 Unknown
Muscle aches	🗆 Yes 🗆 No 🗆 Unknown
Joint ache	🗆 Yes 🗆 No 🗆 Unknown
Loss of appetite	🗆 Yes 🗆 No 🗆 Unknown
Loss of smell (anosmia) or taste (ageusia)	🗆 Yes 🗆 No 🗆 Unknown
Nose bleed	🗆 Yes 🗆 No 🗆 Unknown
Fatigue	🗆 Yes 🗆 No 🗆 Unknown
Seizures	🗆 Yes 🗆 No 🗆 Unknown
Altered consciousness	🗆 Yes 🗆 No 🗆 Unknown
Other neurological signs	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify
Other symptoms	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify:

5. Contact pre-existing condition(s)					
Pregnancy	🗆 Yes 🗆 No 🗆 Unknown				
	If Yes, specify trimester:				
	First Second Third Unknown				

Complete a ne	w line for each spe	cimen collected an	d each type of test do	one:			•
Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	//	//	<ul> <li>Nasal swab</li> <li>Throat swab</li> <li>Nasopharyngeal swab</li> <li>Saliva</li> <li>Other, specify:</li> </ul>	<ul> <li>PCR</li> <li>Whole genome sequencing</li> <li>Partial genome sequencing</li> <li>Other, specify</li> </ul>	<ul> <li>POSITIVE for SARS-CoV-2</li> <li>NEGATIVE for SARS-CoV-2</li> <li>POSITIVE for other pathogens</li> <li>Please specify which</li> </ul>	//	<ul> <li>Yes</li> <li>If Yes, specify date</li> <li>//</li> <li>If Yes, name of the laboratory:</li> <li>No</li> </ul>

Complete a ne	w line for each spe	cimen collected an	d each type of test	done:			Specimens
Laboratory	Date sample	Date sample					shipped to other
identification	collected	received			Result (SARS-CoV-2	Result date	laboratory for
number	(dd/mm/yyyy)	(dd/mm/yyyy)	Type of sample	Type of test	antibody titres)	(dd/mm/yyyy)	confirmation
	//	//	🗆 Serum	Specify type		//	🗆 Yes
			🗆 Saliva	(ELISA/IFA IgM/IgG,	If positive, specify type		If Yes, specify
			🗆 Other,	neutralization	and titre of antibody		date
			specify:	assay, etc.) and	detected (Total, IgM, IgA,		//
				brand:	lgG)		If Yes, name of
							the laboratory:
							□ No

Form B2: Contact follow-up reporting form – for close/casual contacts of confirmed cases (Day 14–21)

7. Final contact classification (at final follow-up)		
Please mark	Never ill/not a case	
	Confirmed secondary case	
	Confirmed subsequent case, note generation _	
	Lost to follow-up	
	Suspected case	
	Probable case	

8. Status of form completion		
Form completed	□ Yes □ No or partially	
	If No or partially, reason:	
	□ Not attempted	
	Not performed	
	Refusal	
	□ Other, specify:	

## Form B3: Symptom diary for close/casual contacts of confirmed COVID-19 cases (Day 1–14)

Symptom diaries will be provided to each contact, for them or legal guardians or school staff to record the presence or absence of various signs or symptoms for a minimum of 14–21 days after the administration of the initial contact questionnaire (Form B1).

The symptom diary template provided below is generic. In the context of the COVID-19 pandemic, symptom diaries may be broadened to include additional symptoms such as vomiting, diarrhoea, abdominal pain, etc., as relevant, and may be altered to include symptom data for longer than 14 days.

In the event the contact develops any of these symptoms, ask him/her to inform your local public health team.

Day						Symptoms	*	
	No symptoms (check if						Loss of taste	Other
	none	Fever	Runny		Sore	Shortness	and loss	symptoms:
	experienced)	≥ <b>38 °C</b>	nose	Cough	throat	of breath	of smell	specify
0	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	□ No	□ No	
1	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
2	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
3	🗆 None	Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
4	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	□ No	□ No	
6	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	🗆 No	□ No	🗆 No	□ No	□ No	
7	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	🗆 No	□ No	□ No	□ No	□ No	
8	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	🗆 No	□ No	□ No	□ No	□ No	
9	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	🗆 No	□ No	□ No	□ No	□ No	
10	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
11	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	🗆 No	□ No	□ No	□ No	
12	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
13	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	□ No	□ No	🗆 No	□ No	
14	🗆 None	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	🗆 Yes	
		□ No	□ No	🗆 No	□ No	□ No	□ No	

\*Please select None for No symptoms. If no symptoms are experienced, then consider the entry complete.

3. For schools

Form C1: School reporting form

COMMENT: Information in this form should be completed every time a new cluster is identified in the school at the investigation team visit.

The visit should start by asking about the class schedule or activities (if staff member) of the primary case and then adapting the questionnaire. The implementation of school measures should be observed according to the recommended Checklist (1) (section 7). The questionnaire will need to be adapted to the school context.

#### 1. Unique School ID/Cluster number (if applicable):

#### 2. Current status of the school

 $\square$  First identification of a case  $\square$  Recurrent  $\square$  Lost to follow-up  $\square$  Unknown

### 3. School type

□ Primary □ Secondary □ Boarding □ Vocational □ Other, specify:

4. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	

5. Interview respondent information		
First name		
Family name		
Occupation/Function		
School address		
Country		
Telephone (mobile) number		
Email		

6. School measures	
Number of pupils – regular class	
Number of pupils – activity class	
Number of pupils – canteen	
Measures to restrict movement in the school and	🗆 Yes 🗆 No 🗆 Unknown
mixing pupil of different grades in place	If Yes, specify:
Physical distancing measures in place	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify:
Enforcement of hand hygiene in place	🗆 Yes 🗆 No 🗆 Unknown
	If Yes, specify: Training pupils/staff, Visual aids, Availability
	(water/soap, alcohol-based disinfectants)

□ Yes □ No □ Unknown f Yes, specify:
f Yes, specify:
🗆 Yes 🗆 No 🗆 Unknown
f Yes, specify: Training pupils/staff, Visual aids, etc.
🗆 Yes 🗆 No 🗆 Unknown
f Yes, specify how:
□ Yes □ No □ Unknown
f Yes, specify:
Give details:
⊐ Yes □ No □ Unknown
f Yes, specify:
🗆 Yes 🗆 No 🗆 Unknown
f Yes, specify:
⊐ Yes □ No □ Unknown
f Yes, specify:
Specify:

#### 7. Implementation of measures according to the Checklist (1)

□1. Promote and demonstrate regular hand washing and positive hygiene behaviours and monitor their uptake.

- Ensure soap and safe water is available at age-appropriate hand washing stations.
- Encourage frequent and thorough washing (at least 20 seconds).
- Place hand sanitizers in toilets, classrooms, halls, and near exits where possible.
- Ensure adequate, clean and separate toilets or latrines for girls and boys.

 $\Box$  2. Clean and disinfect school buildings, classrooms and especially water and sanitation facilities at least once a day, particularly surfaces that are touched by many people (railings, lunch tables, sports equipment, door and window handles, toys, teaching and learning aids etc.).

□ 3. Increase air flow and ventilation where climate allows (open windows, use air conditioning where available, etc.).

□ 4. Post signs encouraging good hand and respiratory hygiene practices.

 $\Box$  5. Ensure trash is removed daily and disposed of safely.

## Reference

- UNICEF, WHO, IRCF. Key messages and actions for COVID-19 prevention and control in schools. New York: United Nations Children's Fund; 2020 (UNICEF/UN1220408/Pacific; <u>https://www.who.int/docs/default-source/coronaviruse/key-messages-and-actions-for-covid-19-prevention-and-control-in-schools-march-2020.pdf?sfvrsn=baf81d52\_4</u>, accessed 4 June 2020).
- 2. Johansen TB, Astrup E, Solveig J, Hege N, Barton DB, Klingenberg C et al. Infection prevention guidelines and considerations for paediatric risk groups when reopening primary schools during COVID-19 pandemic, Norway, April 2020. EuroSurveill. 2020;25(22):2000921. doi:10.2807/1560-7917.ES.2020.25.22.2000921.

## 4. Reporting forms: completion guidance

These notes are to provide guidance in completing the forms. It is suggested that the investigations could be divided into teams – these could include:

- a "case reporter" team;
- a "contact reporter" team; and
- **A "go to" team** who would liaise with additional data sources other than the case or contact, such as hospitals, laboratories, etc.

#### Form A1: Case initial reporting form – for confirmed COVID cases (Day 1) and Form A2: Case followup reporting form – for confirmed COVID cases (Day 14)

These forms should be completed by the "Case reporter" team.

Section	Sources	Verified against
Final case classification	Case reporter/hospital	
Reporter details	Case reporter	
Informant details	Informant	
Patient details	Informant	
Outcome/status	Informant	Statistical data, mortality, GP/hospital
Presenting illness	Informant	Health-care provider/review of medical records
Clinical course/complications	Informant/interview with health-care provider	Review of medical records
Interaction with national security system	Informant/hospital	National social health information system
Reference test results	Testing laboratory	Laboratory database
Bacterial infections	Testing laboratory	Laboratory database

# Form B1: Contact initial reporting form – for close/casual contacts of confirmed COVID-19 cases (Day 1)

This form should be completed by the "Contacts reporter" team and should be completed after the initial case report form (A1) has been completed by the "Case reporter" team, ideally within 24 hours.

Section	Sources	Verified against
Reporter details	Contact reporter	
Informant details	Informant	
Contact details	Informant	
Exposure information	Informant	
Illness in contacts	Informant	Health-care provider/review of medical records
Outcome/status	Informant	Statistical data, mortality, GP/hospital
Case classification	Contact reporter	

Virological tests	Testing laboratory	Laboratory database
Medical history	Informant	Health-care provider/GP/review of
		medical records

# Form B2: Contact follow-up reporting form – for close/casual contacts of confirmed COVID-19 cases (Day 14-21)

This form should be completed by the "Contacts reporter" team.

Section	Sources	Verified against
Reporter details	Contact reporter	
Informant details	Informant	
Final contact classification	Contact reporter	
Exposure information	Informant	
Illness in contacts	Informant	Health-care provider/review of medical records
Clinical course/complications	Informant/interview with health-care provider	Review of medical records
Virological tests	Testing laboratory	Laboratory database

#### Form B3: Symptom diary for close/casual contacts of confirmed COVID-19 cases (Day 1–14)

This form should be completed by the contacts themselves or by the parents/legal tutor/guardian for children.

Symptom diaries will be provided to each close contact for them to record the presence or absence of various signs or symptoms for a minimum of 14 days after the administration of the baseline questionnaire (Form B1).

The symptom diary template provided is generic. In the context of a new virus with uncertain clinical presentation and spectrum, symptom diaries may be broadened to include vomiting, diarrhoea, abdominal pain, etc., as relevant, and may be altered to include symptom data for longer than 14 days.

In the event a contact develops any of these symptoms, he or she needs to inform your local public health team.

#### Form C1: School reporting form (Day 1)

This form should be completed by the "Contacts reporter" team.

Section	Sources	Verified against
Reporter details	Contact reporter	
Informant details	Informant	
Measures in place	Informant	SOP available

# Appendix B: Informed consent and assent forms templates

## Informed consent form

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

- 1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the requirements of their particular investigation and those of their national and institutional regulations. **The logo of the institution must be used on the ICF.**
- 2. The informed consent form consists of two parts: the information sheet and the consent certificate.
- 3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.
- 4. This template includes examples of key questions that may be asked at the end of each section, which could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.
- 5. In this template:
  - square brackets indicate where specific information is to be inserted;
  - bold lettering indicates sections or wording that should be included; and
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms.

TEMPLATE ON FOLLOWING PAGE

#### [YOUR INSTITUTIONAL LETTER HEAD]

[Informed Consent Form for \_\_\_\_\_]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the investigation titled. " Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)")

[Name of Principle Investigator] [Name of Organization] [Name of Sponsor] [Name of Project and Version]

This Informed Consent Form has two parts:

- I. Information Sheet (to share information about the study with you)
- II. Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

## **Part I: Information Sheet**

#### Introduction

Briefly state who you are and explain that you are inviting them to have their child participate in the investigation being conducted. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

#### Purpose

Explain<u>in lay terms</u> why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

#### **Type of Research Intervention**

Briefly state the intervention. This will be expanded upon in the procedures section.

#### **Selection of Participants**

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

#### **Voluntary Participation**

Indicate clearly that they can choose for their child to participate or not and reassure there will be no academic or health impact on the child if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

#### Procedure

Explain what each of the steps or procedures involve. Indicate when the investigation will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

Explain the type of questions that the participants are likely to be asked in the interviews or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these.

#### Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

#### **Risks and Discomforts**

Explain any risks or discomforts including the collection of blood samples and any limits to confidentiality.

#### Benefits

Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

#### Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the investigation. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined in accordance with national regulations.

#### **Confidentiality:**

Explain how the investigation team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality.

#### **Sharing of Research Findings**

Include a statement indicating that the individual findings will be shared with the participant and the overall findings of the investigation will be shared in a timely fashion with the school. In the latter, all confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the overall findings of the investigation will be shared more broadly, for example, through publications and conferences, again on the condition that confidential information will remain confidential.

#### Right to refuse or withdraw

Explain again the voluntary nature of consent - a participant can refuse to participate or withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

If a participant decides to drop out, participants need to inform the investigation team as soon as possible. Any of the previously collected remaining samples and data will be discarded except if the participant informs the investigation team that they can be kept for the purpose of this specific investigation.

#### Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

## **PART II: Certificate of Consent**

#### **Certificate of Consent**

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian \_\_\_\_\_

Signature of Parent of Guardian\_\_\_\_\_

Date \_

Day/month/year

#### If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness\_\_\_\_\_

Signature of witness \_\_\_\_\_

Date \_

Day/month/year

AND Thumb print of participant



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done: 1.

2.

Ζ.

3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant

Print Name of Researcher/person taking the consent\_\_\_\_\_\_

An Informed Assent Form will \_\_\_\_\_ OR will not \_\_\_\_\_ be completed.

Informed assent form (for children/ minors)

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

- 1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the institution must be used on the ICF.**
- 2. The informed consent form consists of two parts: the information sheet and the consent certificate.
- 3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.
- 4. This template includes examples of key questions that may be asked at the end of each section, that could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.
- 5. In this template:
  - square brackets indicate where specific information is to be inserted;
  - bold lettering indicates sections or wording that should be included; and
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms.

TEMPLATE ON FOLLOWING PAGE

#### [YOUR INSTITUTIONAL LETTER HEAD]

An Informed Assent Form does <u>not</u> replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for \_\_\_\_\_]

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the investigation titled. " Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)")

[Name of Principle Investigator] [Name of Organization] [Name of Sponsor] [Name of Project and Version]

This Informed Assent Form has two parts:

- Information Sheet (gives you information about the study)
- Certificate of Assent (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

# **Part I: Information Sheet**

#### Introduction

This is a brief introduction to ensure the child knows who you are and that this is an investigation to understand the spread of COVID-19 in the school setting. Give your name, say what you do and clearly state that you are undertaking the investigation. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

#### Purpose: Why are you doing this research?

Explain the purpose of the research in clear simple terms.

#### Choice of participants: Why are you asking me?

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

#### Participation is voluntary: Do I have to do this?

State clearly and in child-friendly language that the choice to participate is theirs and reassure there will be no academic or health impact if they choose not to participate. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

#### I have checked with the child and they understand that participation is voluntary \_\_(initial)

#### Procedures: What is going to happen to me?

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

#### I have checked with the child and they understand the procedures \_\_\_\_\_(initial))

#### Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

#### Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

#### I have checked with the child and they understand the risks and discomforts \_\_\_\_\_(initial)

#### Benefits: Is there anything good that happens to me?

Describe any benefits to the child.

#### I have checked with the child and they understand the benefits\_\_\_\_\_ (initial)

#### Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the investigation. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined in accordance with national regulations.

#### Confidentiality: Is everybody going to know about this?

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

#### Compensation: What happens if I get hurt?

Describe to the ability of the child to understand and explain that parents have been given more information.

#### Sharing the Findings: Will you tell me the results?

Describe to the ability of the child to understand that the findings as they relate to the child, as well as the overall findings of the investigation will be shared in a timely fashion, but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

#### Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You may want to re-emphasize that participation is voluntary and any limits to this. The child can refuse to participate or withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team.

If a participant decides to drop out, participants need to inform the investigation team as soon as possible. Any of the previously collected remaining samples and data will be discarded except if the participant informs the investigation team that they can be kept for the purpose of this specific investigation

#### Who to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

#### If you choose to be part of this research, I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the investigation, if you wish to. Do you have any questions?

# **PART 2: Certificate of Assent**

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR take part in the research and I have <u>not</u> sigr

I do not wish to take part in the research and I have <u>not</u> signed the assent below.\_\_\_\_\_(initialled by child/minor)

Only if child assents: Print name of child \_\_\_\_\_

Signature of child: \_\_\_\_\_

Date:\_\_\_\_\_

day/month/year

#### If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent)	AND	Thumb print of participant
Signature of witness		
Date		
Day/month/year		

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher\_\_\_\_\_

Signature of researcher\_\_\_\_\_

Date\_

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

- 1.
- 2.

3.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent\_\_\_\_\_

Signature of Researcher /person taking the assent \_\_\_\_\_\_

Date \_\_\_

Day/month/year

Copy provided to the participant \_\_\_\_\_(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent \_\_\_Yes \_\_\_No \_\_\_\_(initialed by researcher/assistant)

Additional possible consent forms, if the investigation calls for storage and future use of samples

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

- 1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the requirements of their particular investigation and to those of the national and institutional regulations. **The logo of the institution must be used on the ICF.**
- 2. The informed consent form consists of two parts: the information sheet and the consent certificate.
- 3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.
- 4. This template includes examples of key questions that may be asked at the end of each section, that could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.
- 5. In this template:
  - square brackets indicate where specific information is to be inserted;
  - bold lettering indicates sections or wording that should be included; and
  - standard lettering is used for explanations to researchers only and must not be included in your consent forms.

TEMPLATE ON FOLLOWING PAGE

#### Additional Consent to [Name of Project]

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the investigation titled. " Schools and other educational institutions transmission investigation protocol for coronavirus disease 2019 (COVID-19)")

#### This Statement of Consent consists of two parts:

- Information Sheet (to share information about unused samples with you)
- Certificate of Consent (to record your agreement)

You will be given a copy of the full Statement of Consent

# Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/ sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. <u>Use lay terms to</u> explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something, they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/ sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

#### **Right to Refuse and Withdraw**

Inform the participant that they may withdraw permission at any time and provide them with the name, address, and number of the person and sponsoring institution to contact. Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way.

#### Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

# Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
I want my [TYPE OF SAMPLE] sample to be destroyed after years.
I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

#### AND (if the sample is to be stored)

I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project: [give name of current research]

I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved

I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

11

11

I want my identity to be removed from my (TYPE OF SAMPLE) sample.

I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant\_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_

Day/month/year

#### If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness\_\_\_\_\_

AND	Thumb	print of	<sup>f</sup> participant
			P

Signature of witness \_\_\_\_\_

Date \_\_\_

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent\_\_\_\_\_

Signature of Researcher /person taking the consent\_\_\_\_\_

Date \_

Day/month/year

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WHO reference number: WHO/2019-nCoV/Schools transmission/2020.1