COVID-19 Module Guideline v1.0

Protocol

Module Purpose

A collection of measures to capture essential phenotypes associated with COVID-19 related biomedical research.

Guideline Description

The COVID-19 module can be used to collect essential phenotypes associated with COVID-19 related research, including: COVID-19 Exposure History; Symptoms and Signs; Comorbidities; COVID-19 Diagnoses and Treatments. The following document establishes guidelines (particularly applicable in Africa) on how to use the module and collect detailed, relevant and harmonized phenotype and exposure data for research.

The guideline is subdivided into recommendations for collecting core phenotypes (phenotypes incorporated from the H3Africa Standard, Protocols A through F) and COVID-19 & MIS-C specific phenotypes (Protocols 1 through 13). These protocols are listed below:

Protocol	**Phenotypes**	**Protocol**	**Phenotypes**
A	Demographics	5	Vital Signs
B	Anthropometrics	6	COVID-19 Diagnosis
C	Smoking Exposure	7	MIS-C Diagnosis
D	Smoking Status	8	Follow-Up
E	Alcohol Exposure	9	Death
F	Alcohol Use	10	Hospitalisation
1	Pregnancy	11	Medication History
2	Exposure History	12	Medication Log
3	Comorbidities	13	Lab Tests
4	Disease Symptoms		

Important Notes

1. The module employs branching logic, therefore, we recommend that it is completed in order, as some variables may or may not appear OR accept input based on the input of previously listed variables. Protocol A and 1, in particular, are crucial to complete in this regard.

2. Some branching logic (specifically related to date of birth/age and current pregnancy) affects the display of items relevant to adult or paediatric participants across multiple protocols.

3. Protocol 11 and 12 both collect information related to medication. Based on the study design, one or both of these protocols may be employed to collect such information.

4. Consistent codes are recommended for the identification of missing data, and these are incorporated into all Protocols discussed below. We recommend the use of 'Temporarily unavailable' for pending results in Protocol 6 and 13. Codes for Missing Data are specified below:

Code	Value Label
-991	No information
-992	Asked but unknown
-993	Temporarily unavailable
-994	Not asked
-995	Refused
-998	Not applicable

Recommendations - Core Phenotypes

Protocol A: Demographics

The protocol enables the collection of essential participant demographics such as age, gender, and language.

Questions	Date of birth? Age*: Are you male or female? **Response Options**: Male; Female; Other In which country were you born? What is your native language? What is your ethnic or tribal affiliation?

Notes	- **Date of birth** should be collected in following format - DD-MM-YYYY - Whenever possible participant date or birth should be captured and verified with official documentation. - **Age** can be automatically calculated based on the date of birth. - If date of birth is unavailable, estimated age may be provided. - The **sex** field collects the biological sex of a participant, and should not be confused with gender identification. The option "Other" was used as a sensitive manner to identify Intersex participants who may be sensitive due to stigma about their biological sexual status - The participant's **home/native language** that they were raised with should be completed in the language field. If the participant has multiple native languages, complete the field with the most commonly used native tongue – the language they consider their home language - The participant's original **ethnic or tribal affiliation** should be collected in the ethnic affiliation field. If the participant identifies with multiple ethnic tribes, document the primary one or collect the one the participant first identified with growing up. - It is recommended that the Ethnolinguistic Ontology (ELO) is used for collection of the language and ethnic affiliation fields. - If ELO is not available or applicable, local standards should be used as potential response options.
Questions	What is your father's country of birth? What is your father's native language? What is your father's ethnic or tribal affiliation?
	What is your mother's country of birth? What is your mother's native language? What is your mother's ethnic or tribal affiliation?
Notes	- If the participant is adopted or orphaned and unable to supply this information, this should be recorded and it may be worth including a field on the demographics form to accommodate this possibility.

Protocol B: Anthropometrics

The protocol enables the collection of anthropometric data, including height and weight, as well as waist and head circumference.

Questions	Height measurement #1: Height measurement #2: Height measurement #3: Average height: How tall are you?*
Notes	- **Height** is the distance from the top of the participant's head to the heels of his or her feet (i.e., the vertical length). Three separate height measurements need to be taken in the same session and then averaged to get an accurate height measurement. - Height is measured in cm using a stadiometer, if possible. - Participant's should only be asked to provide their height if measuring is not possible at all. Self-reported height is considered to be less accurate and should

	only be used if measured height could not be obtained.
	- Detailed protocols for measuring height can be found in PhenX:
	  - **Standing Height Protocol:** https://www.phenxtoolkit.org/index.php?pageLink=browse.protocoldetails&id=20703
	  - **Measuring height in seated position** for participants unable to stand: https://www.phenxtoolkit.org/index.php?pageLink=browse.protocoldetails&id=20701

Questions	Weight measurement #1: Weight measurement #2: Weight measurement #3 Average weight (kg): Is the participant wearing a cast or medical prosthesis? Location of cast or medical prosthesis: Is the participant wearing street clothes during the weight measurements?

Notes	- **Weight** is measured in kg using a using a floor scale. The instrument should be calibrated daily using standardized weights, and a log of calibration results should be maintained. Repeat this 3 times and each time record the weight in the 3 separate measurement boxes.
	- **Special Situations**:
	  - Small children: Infants and toddlers who cannot stand alone on the scale will be weighed with an adult, or with an infant's scale. If an adult is holding the child, then the adult guardian or the health technician will stand alone on the scale so the scale can be tared. This sets the scale readout to zero. The child is then handed to the adult and the child's weight is measured.
	  - Note that special consideration may be needed for participants whose weight exceeds the capacity of the study scale. For example, weight can be obtained using two portable scales.
	- Participants should only be asked to provide their weight if measuring is not possible at all. Self-reported weight is considered to be less accurate and should only be used if measured weight could not be obtained.

Questions	Waist Circumference Measurement #1: Waist Circumference Measurement #2: Waist Circumference Measurement #3: Waist Circumference Average Measurement:
Notes	- **Waist circumference** should only be collected for participants ranging from the Childhood to Adult Life Stages (see **Life Stage**) - Waist circumference, measured in cm using a flexible, non-stretch measuring tape, is a measurement taken around the abdomen at the level of the belly button.

Protocol C: Smoking Exposure

The protocol is strictly for use in participants younger than 18 and enables the self-reported collection of household smoking exposure.

Questions	Does anyone in the household smoke cigarettes or other tobacco-based products?

	Response Options: Yes; No (If YES) How many members in the household smoke? (If YES) How frequently do they smoke? **Response Options**: Once a day, More than once a day, once or twice a week, once or twice a month
Notes	- The fields collect information regarding any smoking which occurs within the participant's household. - This protocol is strictly applicable for the Infancy to Adolescence Life Stages.

Protocol D: Smoking Status

The protocol enables the self-reported collection of smoking use in participants in the Adolescence and Adult life stages.

Questions	Have you smoked at least 1/100 cigarette(s) in your entire life?* **Response Options**: Yes; No How old were you when you first started smoking cigarettes?
Notes	- For adolescents, the first question should be specified as 1 cigarette. - For adults, the first question should be specified as 100 cigarettes. - For adults, It is assumed that people who have smoked less than 100 cigarettes in their lifetime do not have a significant smoking status to investigate. - Proceed to the second and subsequent fields only if a participant answers Yes in the first field.
Questions	What type of smoker would you currently say you are: **Response Options**: An EVERY day smoker; A FAIRLY REGULAR (some days) smoker; A FORMER smoker Have you EVER smoked cigarettes EVERY DAY for at least 6 months? **Response Options**: Yes; No
	On the days that you smoke, on average, how many cigarettes do you smoke? **OR** If you are a former smoker, on the days that you smoked, on average, how many cigarettes did you smoke? Over the past 30 days, on how many days did you smoke? **OR** If you are a former smoker, on average, on how many days did you smoke in a month? (FOR Former Smokers): About how long has it been since you COMPLETELY quit smoking cigarettes?
	Tobaccos Use: [Have you smoked at least 50 cigars? Have you smoked a pipe at least 50 times? Have you used snuff (such as Skoal, Skoal Bandit or Copenhagen) at least 20 times? Used chewing tobacco (such as Redman, Levi Garrett or Beechnut) at least 20 times?] **Response Options**: Yes; No

Notes	- Questions related to tobacco use (not in cigarettes) must be completed by all participants regardless of specified cigarette usage. - This protocol is strictly applicable for the Adolescence and Adult Life Stages.

Protocol E: Alcohol Exposure

The protocol is strictly for use in participants younger than 18 and enables the self-reported collection of household alcohol exposure.

Questions	Does anyone in the household drink alcohol? **Response Options**: Yes; No (If YES) How many members in the household drink alcohol? (If YES) How frequently do they drink alcohol? **Response Options**: Once a day, More than once a day, once or twice a week, once or twice a month
Notes	- The fields collect information regarding any alcohol use which occurs within the participant's household. - This protocol is strictly applicable for the Infancy to Adolescence Life Stages.

Protocol F: Alcohol Use

The protocol enables the self-reported collection of alcohol use in participants in the Adolescence and Adult life stages.

Questions	In your entire life, have you had at least 1 drink of any kind of alcohol? **Response Options**: Yes; No (if YES) How old were you when you first started drinking alcohol?
	During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage? On the days that you drank during the past 30 days, how many drinks did you usually have each day? What was the LARGEST number of drinks that you ever drank in a single day?
Notes	- This protocol is strictly applicable for the Adolescence and Adult Life Stages. - Interviewers need to be sensitive to the participant's culture and religion and be aware that some participants may be reluctant to answer these questions truthfully. - Participants should be reassured that their answers will be kept confidential - Studies should have a defined quantity or way to measure drinks as examples for participants. One "standard" drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol. In practice, the total volume differs between types of alcohol. For more information, see: https://www.phenxtoolkit.org/protocols/view/30301

Recommendations - COVID-19 & MIS-C Specific Phenotypes

Protocol 1: Pregnancy

The protocol enables the retrospective collection of pregnancy status or recent pregnancy from female research participants.

Questions	Has the participant had a pregnancy outcome in the past 6 months? **Response Options**: Yes; No (if YES) Date of most recent pregnancy outcome:
	Is the participant currently pregnant? **Response Options**: Yes; No (if YES) Estimated due date OR assessed gestational weeks: (if YES) is the number of foetuses known? (if YES) If Yes, number of foetuses:
Notes	- This protocol is strictly applicable to female research participants. - Protocol may be applied to both adult and adolescent research participants. - Dates should be collected in following format - DD-MM-YYYY - Gestational weeks should only be collected if due date is unavailable or not known.
Questions	Gravida (number of total pregnancies): Para gravida (number of pregnancies >20 gest. weeks): Number of vaginal deliveries: Number of caesarean deliveries:
Notes	- The above questions collect information related to a participant's pregnancy history. - This protocol is strictly applicable to female research participants. - Protocol may be applied to both adult and adolescent research participants.

Protocol 2: Exposure History

The protocol enables the retrospective collection of potential COVID-19 exposure, including travel history, isolated exposure events and occupational exposure.

Questions	Has the participant travelled in the last 20 days? **Response Options**: Yes, domestic; Yes, international; Yes, domestic and international; No (If INTERNATIONAL) Indicate number of countries visited (include stopover countries): Please select the countries visited in the last 20 days (order descriptive from recent to least recent):
Notes	- Domestic travel involves travelling between provinces or states within the same country. - International travel involves travelling between different countries.

Questions	Has the participant recently attended or been part of a mass gathering? **Response Options: Yes; No** (If YES) What type? **Response Options**: Convention; Religious; Social (e.g. funeral, wedding, party); Sporting Event; Protest; Other (If OTHER) Please specify?

Notes	- Mass gathering:
	  - An event attended by a sufficient number of people to strain the planning and response resources of the host community, city, or nation hosting the event.
	  - An occasion either organized or spontaneous, in which a sufficient number of people assembled at a particular location for a specific purpose and for a defined period of time.
	- A number of examples of mass gatherings are provided in the response options.

Question	Has the participant been around or spent time with anyone who has tested positive for COVID-19 during their infectious period (14 days prior to testing, and duration of positive status)? **Response Options**: Yes; No
Notes	- It should be clarified that the interaction collected here is limited to interaction with a contact who has/had an active, confirmed bout of COVID-19. Individuals who may have contracted COVID-19 long after the interaction period, for example, should not be included here.
Questions	How many people live in the participant's household? Has anyone in the participant's household tested positive for COVID-19? **Response Options**: Yes; No
	Education Level: (Is the participant/Are you) currently attending school? **Response Options**: Yes; No (if Yes) What type of school? **Response Options**: Early Learning Centre / Nursery / Creche Preschool / Kindergarten / Grade R Public Primary school (Grade 1 - 7) Private Primary school (Grade 1 - 7) Public Secondary school (Grade 8 - 12) Private Secondary school (Grade 8 - 12) Special school / School for children with disabilities Homeschool / Cottage school Tertiary school / College / Technikon /University
Notes	- These questions are limited to pediatric research participants

<table>
<tr><td>Questions</td><td>Occupation:
Is the participant currently a student?
Response Options: Yes; No
Is the participant currently employed?
Response Options: Yes; No
(If Employed) What is the participant's field of work?
Response Options:
Retail/Wholesale; Restaurant/Food; Communications/IT; Agriculture; Mining; Manufacturing; Financial Services; Textile; R&D; Education; Healthcare; Other
(If Other) Please specify:
(If Healthcare) What is the participant's profession?
Response Options:
Nurse; Medical Practitioner (Doctor, Surgeon, Dentist); Hospital Porter; Paramedic; Laboratory Worker (Medical Facility); Administration (Medical Facility); Financial Services (Medical Facility); Pharmacist; Other
(If Other) Please specify:</td></tr>
<tr><td>Notes</td><td>- These questions are limited to adult research participants.
- Healthcare professions include both healthcare professionals and any profession which involves working in or around a healthcare setting.
- Some Examples of professions in each work field:
<table><tr><td>Field</td><td>Examples</td></tr><tr><td>Retail/Wholesale</td><td>Store Manager, Cachier , Inventory Control Specialist , Electrical Goods Supplier Wholesale, Driver, Sales Workers</td></tr><tr><td>Restaurant/Food</td><td>Chef, Baker, Butcher, Restaurant Manager, Dietitian, Nutritionist, Server, Busser</td></tr><tr><td>Communications / IT</td><td>Human Resources Specialist, Social Media Manager, Business Reporter, Web Developer, Systems Analyst , IT Technician</td></tr><tr><td>Agriculture</td><td>Farmer, Agricultural Engineer, Food Scientist, Agronomist, Agricultural Operations Manager</td></tr><tr><td>Mining</td><td>Geologist, Electricians, Contract Miner, Diamond Driller, Environmental Coordinator</td></tr><tr><td>Manufacturing</td><td>Mechanical Engineer. Cad Draftsman, Quality Control Inspector, Assembly ne Worker, Machine Operator</td></tr><tr><td>Financial Services</td><td>Customer Service, financial adviser, Banker, Accountant, Insurance Agent</td></tr><tr><td>Textile</td><td>Print Designer, Production Equipment Operator, Fabric Development Specialist, Design Technician</td></tr><tr><td>R&D</td><td>Researchers, Scientists, Project Managers, Marketing Experts</td></tr><tr><td>Education</td><td>Teacher, College Professor, Librarian, Academic Advisor, Admission Counselor, School Psychologist Education Consultant</td></tr></table></td></tr>
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Protocol 3: Comorbidities

This protocol enables the collection of co-occurring disease and(or) past diseases that may influence the severity of a COVID-19-related infection.

<table>
<tr><td>Questions</td><td>Has the participant been clinically diagnosed with any of the following cardiovascular diseases?
- Arrhythmia; Congestive heart failure; Myocardial infarction Type I; Myocardial infarction Type II; Obesity; Peripheral vascular disease
Response Options: Yes; No
Has the participant been clinically diagnosed as having experienced a stroke?
Response Options: Yes; No</td></tr>
<tr><td>Notes</td><td>- The disease specific cardiovascular questions are limited to adult research participants
- For paediatric participants a test specify field is used instead to collect cardiovascular disease
- Cardiovascular Disease (CVD) is a condition involving the cardiovascular system including the heart; blood vessels; or pericardium. The most common type of heart diseases in pediatrics is Congenital Heart Disease (CHD) that include heart valve disorders, hypoplastic left heart syndrome, ventricular dental defects, patent ductus arteriosus and tetralogy of Fallot. Another examples of pediatrics CVD are Atherosclerosis, Arrhythmias, Heart murmurs, Pericarditis, and Rheumatic heart disease.
- Adult CVD descriptions:
<table>
<tr><td>Disease</td><td>Description</td></tr>
<tr><td>Arrhythmia (Cardiac Arrhythmia)</td><td>Any variation from the normal rate or rhythm in the heart. Symptoms may include, a fluttering in chest, a racing heartbeat, a slow heartbeat, chest pain, and shortness of breath.*</td></tr>
<tr><td>Congestive heart failure (CHF)</td><td>A failure of the heart to pump a sufficient amount of blood to the body tissues, resulting in tissue congestion and edema. Symptoms may include shortness of breath, pitting edema, enlarged tender liver, engorged neck veins, and pulmonary rales.*</td></tr>
<tr><td>Myocardial infarction Type I</td><td>A spontaneous myocardial infarction related to ischaemia due to a primary coronary event such as plaque erosion and/or rupture, fissuring, or dissection.*</td></tr>
<tr><td>Obesity</td><td>Having a high amount of body fat (body mass index [BMI] of 30 or more).*</td></tr>
<tr><td>Peripheral vascular disease</td><td>Any disorder affecting blood flow through the veins or arteries outside of the heart or brain and causes them to narrow, block, or spasm. It causes pain and fatigue, often in your legs, and especially during exercise.*</td></tr>
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<tr><td></td><td>
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<tr><td>Stroke</td><td>A stroke occurs when the blood supply to part of your brain is interrupted or reduced, preventing brain tissue from getting oxygen and nutrients. A stroke is a medical emergency, and prompt treatment is crucial. *</td></tr>
<tr><td colspan="2">*Adult-only collections</td></tr>
</table>
</td></tr>
<tr><td>Questions</td><td>Has the participant been clinically diagnosed with any of the following pulmonary diseases?
- Sleep Apnea; Asthma; Chronic obstructive pulmonary disease; Cystic Fibrosis
Response Options: Yes; No</td></tr>
<tr><td></td><td>Has the participant been clinically diagnosed with a respiratory infection in the previous 4 weeks?
Response Options: Yes; No</td></tr>
<tr><td>Notes</td><td>- The respiratory infection field is limited to participants younger than 18.
- Disease descriptions:
<table>
<tr><th>Disease</th><th>Description</th></tr>
<tr><td>Sleep Apnea</td><td>A disorder which causes cessation of breathing for short periods during sleep. It can occur at any age but it is more frequent in people over forty. Symptoms include loud snoring, gasping for air during sleep, difficulty staying asleep, excessive daytime sleepiness, and morning headache.</td></tr>
<tr><td>Asthma</td><td>A chronic respiratory disease manifested as difficulty breathing. Symptoms may include shortness of breath , chest tightness or pain, and coughing or wheezing attacks.</td></tr>
<tr><td>Chronic Obstructive Pulmonary Disease (COPD)</td><td>A chronic and progressive lung disorder characterized by the loss of elasticity of the bronchial tree and the air sacs, destruction of the air sacs wall, thickening of the bronchial wall, and mucus accumulation in the bronchial tree. The pathologic changes result in the disruption of the air flow in the bronchial airways. Signs and symptoms include shortness of breath, wheezing, productive cough, and chest tightness</td></tr>
<tr><td>Cystic Fibrosis (CF)</td><td>A congenital metabolic disorder affecting the exocrine glands. Symptoms usually appear in childhood, and include meconium ileus, poor growth despite good appetite, malabsorption and foul bulky stools, chronic bronchitis with cough, recurrent pneumonia, bronchiectasis, and emphysema.</td></tr>
<tr><td>Respiratory Infection</td><td>A respiratory infection is a viral or bacterial infection that may interfere with normal breathing. It can affect the upper respiratory system, which starts at the sinuses and ends at the vocal cords, or the lower respiratory system, which starts at the vocal cords and ends at the lungs. Collected for all life stages (excluding Adult).</td></tr>
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<table>
<tr><td>Question</td><td>Has the participant been clinically diagnosed with any of the following organ-related diseases?
- Asplenia; Chronic Kidney Disease (CKD); Liver Disease; Gallbladder Disease; Pancreatic Disease; Sickle Cell Disease
Response Options: Yes; No</td></tr>
<tr><td>Notes</td><td>- Diseases listed differ between adult and pediatric templates.
- Disease descriptions:
<table>
<tr><td>Disease</td><td>Description</td></tr>
<tr><td>Asplenia</td><td>The anatomic absence of the spleen or functional asplenia secondary to a variety of disease states.</td></tr>
<tr><td>Chronic Kidney Disease (CKD)</td><td>The impairment and the gradual loss of the renal function. Symptoms may include nausea, vomiting, loss of appetite, changes in urination frequency , decreased mental sharpness, swelling of feet and ankles.</td></tr>
<tr><td>Liver Disease</td><td>Pathological processes of the liver. Symptoms may include, yellowish skin and eyes (jaundice), abdominal pain swelling, swelling in the legs and ankle, dark urine color, pale stool color and chronic fatigue.</td></tr>
<tr><td>Gallbladder Disease</td><td>the impairment of bile flow, gallstones in the biliary tract, infections, and neoplasms</td></tr>
<tr><td>Pancreatic Disease</td><td>A disorder that affects the pancreas such as pancreatitis and pancreatic insufficiency.</td></tr>
<tr><td>Sickle Cell Disease</td><td>A blood disorder characterized by the appearance of sickle-shaped red blood cells and anemia.</td></tr>
</table></td></tr>
<tr><td>Questions</td><td>(If CKD YES) what is the participant's most recent creatinine measurement?
Date of creatinine measurement:
(If CKD YES) what is the participant's most recent GFR measurement?
Date of GFR measurement:</td></tr>
<tr><td>Notes</td><td>- Dates should be collected in following format - DD-MM-YYYY
- Creatine (in mmol/L) and GFR (in mL/min) measurements should be collected from a qualified medical laboratory facility.</td></tr>
<tr><td>Question</td><td>Has the participant been clinically diagnosed with any of the following mental or brain conditions?
- Anxiety Disorder; Dementia; Depression; Neurological Disease; Substance Abuse Disorder
Response Options: Yes; No</td></tr>
<tr><td>Notes</td><td>- Diseases listed differ between adult and pediatric templates.
- Disease descriptions:
<table>
<tr><td>Disease</td><td>Description</td></tr>
</table></td></tr>
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	<table><tr><td>Anxiety Disorder (Anxiety)</td><td>A category of psychiatric disorders which are characterized by anxious feelings or fear often accompanied by physical symptoms associated with anxiety.</td></tr><tr><td>Dementia</td><td>A cognitive disorder resulting from a loss of brain function affecting memory, thinking, language, judgement and behavior.*</td></tr><tr><td>Depression</td><td>Depression is a mood disorder that causes a persistent feeling of sadness and loss of interest and can interfere with your daily functioning.</td></tr><tr><td>Neurological disorder</td><td>Diseases of the central and peripheral nervous system. This includes disorders of the brain, spinal cord, cranial nerves, peripheral nerves, nerve roots, autonomic nervous system, neuromuscular junction, and muscle.</td></tr><tr><td>Substance Abuse Disorder (Drug Addiction)</td><td>A disease that affects a person's brain and behavior and leads to an inability to control the use of a legal or illegal drug or medication.*</td></tr><tr><td colspan="2">*Adult-only collections</td></tr></table>
Questions	[Has the participant been clinically diagnosed with an Immunological Disorder? Has the participant been clinically diagnosed with Autoimmune Disease? Has the participant been clinically diagnosed with Rheumatologic Disease? Has the participant been clinically diagnosed with Hematological Disease? Has the participant been clinically diagnosed with a chromosomal genetic disorder? Has the participant been clinically diagnosed with Cancer? Has the participant been clinically diagnosed with Malaria?] **Response Options**: Yes; No
Notes	- Disease descriptions: <table><tr><td>Disease</td><td>Description</td></tr><tr><td>Immunological Disorder</td><td>A disease caused by abnormal or absent immunologic mechanisms, whether humoral, cell-mediated, or both</td></tr><tr><td>Autoimmune Disease</td><td>Disorder that is characterized by the production of antibodies that react with host tissues or immune effector cells that are autoreactive to endogenous peptides.</td></tr><tr><td>Rheumatologic Disease</td><td>A hypersensitivity reaction type II disease that involves inflammation or pain in the muscles, joints, or fibrous tissue.</td></tr><tr><td>Hematological Disease</td><td>A disorder of the blood and blood forming tissues.</td></tr><tr><td>Chromosomal genetic disorder</td><td>A disorder which results from a change in the number or structure of chromosomes, such as Down Syndrome.</td></tr></table>

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<tr><td></td><td>
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<tr><td>Cancer</td><td>A disease of cellular proliferation that is malignant and primary, characterized by uncontrolled cellular proliferation, local cell invasion and metastasis.</td></tr>
<tr><td>Malaria</td><td>An infectious disease caused by the presence of protozoan parasites in the red blood cells, and characterized by periodic attacks of chills and fever that coincide with mass destruction of blood cells and the release of toxic substances by the parasite at the end of each reproductive cycle.</td></tr>
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</td></tr>
<tr><td>Questions</td><td>[Has the participant been clinically diagnosed with Kawasaki Disease?
Has anyone in the participant's family been clinically diagnosed with Kawasaki Disease?]
Response Options: Yes; No</td></tr>
<tr><td>Notes</td><td>- These questions are limited to pediatric research participants.
- Kawasaki Disease is a lymphadenitis characterized by swelling of cervical lymph nodes in infants and young children and inflammation of medium-sized blood vessels in the body, Symptoms include fever, ocular conjunctiva, and reddening of lips and(or) oral cavity.</td></tr>
<tr><td>Questions</td><td>Has the participant been clinically diagnosed with Diabetes?
Response Options: Yes; No
(If YES) what is the participant's most recent HbA1c measurement?
Date of HbA1c measurement:</td></tr>
<tr><td></td><td>Has the participant been clinically diagnosed with Hypertension?
Response Options: Yes; No
(If YES) what is the participant's most recent blood pressure measurement
Date of blood pressure measurement:</td></tr>
<tr><td>Notes</td><td>- Dates should be collected in following format - DD-MM-YYYY
- HbA1c measurement (in mmol/mol) should be collected from a qualified medical laboratory facility.
- Blood pressure (in mmHg) should be measured by a qualified healthcare professional.</td></tr>
<tr><td>Questions</td><td>[Has the participant been clinically diagnosed with HIV/AIDS?
(If YES) is the participant currently on ART?]
Response Options: Yes; No
(If YES) what is the participant's most recent Viral Load measurement?
Date of Viral Load measurement:
(If YES) what is the participant's most recent CD4 count?
Date of CD4 count:</td></tr>
<tr><td>Notes</td><td>- Dates should be collected in following format - DD-MM-YYYY
- Viral Load (in number of copies) and CD4 (in cells/µL) measurements should be collected from a qualified medical laboratory facility.
- ART (Antiretroviral Therapy) is a term that describes the daily use of a</td></tr>
</table>

	combination of HIV medicines (called an HIV regimen) to treat HIV infection.
Questions	[Has the participant been clinically diagnosed with TB? Does the participant currently have TB (diagnosis within the last six months)? (If YES) is the participant currently on TB treatment?] **Response Options**: Yes; No
Notes	- **TB** (Tuberculosis) is an infectious disease located in lungs, lymph nodes, pericardium, brain, pleura or gastrointestinal tract. It caused by Mycobacterium tuberculosis, which is transmitted_by droplets released into the air when an infected person coughs or sneezes

Protocol 4: Disease Symptoms

The protocol enables the recording of symptoms which have been associated with both COVID-19 and MIS-C. The protocol can be used longitudinally.

Questions	Has the participant experienced any COVID-19 or MIS-C related symptoms? **Response Options**: Yes; No (if YES) Date of first symptom onset: (If YES) Date of symptoms collection/recording: Signs and Symptoms: **Response:** Yes (ongoing); Yes (previously); No; Don't know (If Other) Please specify:

Notes	- Dates should be collected in following format - DD-MM-YYYY
	- Signs and symptoms include:
	  - Cold Hands/Feet
	  - Hypotension
	  - Hypotonia
	  - Inflammation (Oral/Peripheral)
	  - Irritability
	  - Pale
	  - Paralysis
	  - Photophobia
	  - Prolonged capillary refill time
	  - Seizures
	  - Skin Ulcers
	  - Stiff Neck
	  - Swollen joints
	  - Tachycardia
	  - Tachypnoea
	  - Below average urinary output
	  - Wheezing
	  - Headache
	  - Anosmia (loss of smell)
	  - Sore throat
	  - Cough
	  - Hoarseness
	  - Chest pain or pressure

	- Dyspnea (difficulty breathing) - Fatigue - Myalgia (joint pain) - Loss of appetite - Abdominal pain: - Diarrhea - Fever - The symptom ontology can be consulted for specific symptom definitions: https://www.ebi.ac.uk/ols/ontologies/symp - Unlike other protocols, a missing code should not be applied here, and instead the designated response option should be selected if a symptom is unknown.
Questions	(If DRY OR MUCUS COUGH) number of days with cough: (If FEVER YES) number of days with fever: (If FEVER YES) what is the participant's highest temperature measure? (If FEVER YES) Date of highest temperature measure: (If COUGH YES) Type of cough: **Response Options**: Dry cough; Wet Cough (If RASH YES) Type of rash: **Response Options**: Purpura; Urticaria; Erethemia; Chillblains; Other (If OTHER) Specify other type of rash:

Protocol 5: Vital Signs

The protocol enables the recording of general participant vital signs. The protocol can be used longitudinally.

Questions	Date vital signs observed and recorded::
Notes	- Dates should be collected in following format - DD-MM-YYYY - Vital signs included are listed below:
Questions	Vital Signs: - Temperature (in Celsius) - Heart Rate (in beats/min) - Respiratory Rate (in breaths/min) - Blood Pressure (systolic) (in mmHg) - Blood Pressure (diastolic) (in mmHg) - Dehydration - > Severe; Some; None; Unknown - Capillary Refill Time > 2 seconds -> Yes; No - Oxygen saturation (%): - Oxygen saturation measured on: room air; oxygen therapy - Conscious State (check all that apply) -> Alert; Response to verbal stimuli; Response to painful stimuli; Unresponsive

Notes	- All vital signs should be recorded by a qualified healthcare professional. - **Dehydration**: A condition resulting from excessive loss of water. - **Capillary refill time**: The required for return of color after application of blanching pressure to a distal capillary bed. - **Conscious state**: Sense of awareness of self and of the environment.

Protocol 6: COVID-19 Diagnosis

The protocol enables the recording of information related to the diagnosis (or lack thereof) of COVID-19 with regards to a research participant.

Questions	Has the participant been tested for coronavirus/COVID-19? **Response Options**: Yes; No (If YES) Type of Test: **Response Options**: Diagnostic (Molecular/PCR/Viral); Serological (Antibody); Rapid Diagnostic (Antigen); Other (If Other) Please specify: (If YES) Specimen type: **Response Options**: Nasopharyngeal swab; Blood; Saliva; Other (If Other) Please specify: (If YES) Date specimen collected: (If YES) Date test completed: (If YES) Date result received by participant: (If YES) Result: **Response Options**: Positive; Negative; Not detected;

Notes	- Dates should be collected in following format - DD-MM-YYYY
	- COVID-19 results should be collected from a qualified medical laboratory facility.
	- Participants are classified as COVID-19 positive only following laboratory confirmation; other forms of diagnosis are not applicable here.
	- If results are pending, the relevant missing code should be applied.
	- Test types:
	  - **Diagnostic (Molecular/PCR/Viral)**; is a rRT-PCR test for the detection of nucleic acid from SARS-CoV-2 in upper/lower respiratory specimens. This test detects current infection with high specificity and sensitivity.
	  - **Serological (Antibody)**; is a blood test that detectS if a person has antibodies to SARS-CoV-2. These tests can identify people who may have been infected or have recovered from the COVID-19 infection.
	  - **Rapid Diagnostic (Antigen)**; are immunoassays that detect the presence of a specific COVID-19 viral antigen. Antigen tests are performed on nasopharyngeal or nasal swab specimens. They are relatively inexpensive and can be used at the point-of-care.

Questions	(If POSITIVE) COVID-19 Case severity: **Response Options**: Asymptomatic; Mild; Moderate; Severe (If POSITIVE) Was the participant hospitalized for COVID-19? **Response Options**: Yes; No
Notes	- Dates should be collected in following format - DD-MM-YYYY - Details regarding the participant's COVID-19 prognosis should be assessed by a qualified clinician. - Asymptomatic vs Symptomatic-> Asymptomatic is a term that means without clinical signs or indications that raise the possibility of a particular disorder or dysfunction whilst symptomatic is used to describe the person exhibiting the symptoms of a particular disease.

Protocol 7: MIS-C Diagnosis

The protocol enables the recording of information related to the diagnosis (or lack thereof) of MIS-C with regards to a research participant. The Protocol is only applicable to pediatric research participants.

Questions	[Has the participant been admitted to hospital in the last 3 months? **Response Options**: Yes; No Has the participant been diagnosed with MIS-C? **Response Options**: Yes; No (If NO) Is the participant suspected to have MIS-C? **Response Options**: Yes; No (If YES) Which methods of diagnosis were employed? (check all that apply) **Response Options**: Chest X-ray/CT; ECG; Echocardiography; Physical Signs & Symptoms Assessment; Other (If Other) Please specify: (If YES) Was the participant hospitalized for MIS-C? **Response Options**: Yes; No
Notes	- Participants are classified as MIS-C positive only once diagnosed by a qualified healthcare professional. - Methods of diagnosis refer to the evidence upon which MIS-C diagnosis was based. - Provision is made to add supplementary files related to the methods of diagnosis e.g. Chest X-ray or CT image files.

Protocol 8: Follow Up

The protocol enables the recording of information related to the prognosis of a participant who has been diagnosed with COVID-19 or MIS-C, but not hospitalised.

Questions	Date of follow-up: Type of follow-up? **Response Options**: Physical examination with medical practitioner; Telephonic interview; Mobile data collection app Participant status at follow-up: **Response Options**: Positive, Asymptomatic; Positive, Symptomatic; Death related to or as complication of COVID-19; Death unrelated to COVID-19; Recovered (If DIED) Date of death? Cause of death: **Response Options**: Related to or as complication of COVID-19 Related to or as a complication of MIS-C Other cause of death not linked to COVID-19 Please specify other cause of death:
Notes	- The protocol is only applicable to research participants which were not hospitalized as a result of COVID-19 or MIS-C. - Dates should be collected in following format - DD-MM-YYYY - Asymptomatic vs Symptomatic-> Asymptomatic is a term that means without clinical signs or indications that raise the possibility of a particular disorder or dysfunction whilst symptomatic is used to describe the person exhibiting the symptoms of a particular disease.

Protocol 9: Death

The protocol enables the recording of basic information related research participants that may have died as a result of COVID-19. Should be applied only with appropriate consent confirmed.

Questions	(If DIED) Date of death? Cause of death: **Response Options**: Related to or as complication of COVID-19 Related to or as a complication of MIS-C Other cause of death not linked to COVID-19 Please specify other cause of death:
Notes	- Dates should be collected in following format - DD-MM-YYYY - The protocol is only applicable to research participants which were not

	hospitalized as a result of COVID-19 or MIS-C.

Protocol 10: Hospitalisation

The protocol enables the recording of details related to the hospitalisation of patients diagnosed with either COVID-19 and MIS-C, as well as any complications experienced by patients during hospitalisation.

Questions	Date of hospital admission: Reason for hospital admission: **Response Options**: COVID-19; MIS-C; Other Specify other reason for admission: Was the participant admitted to the General Ward? Was the participant admitted to the High Care Unit? Was the participant admitted to the Intensive Care Unit? **Response Options**: Yes; No Number of days in General Ward: Number of days in High Care Unit: Number of days in Intensive Care Unit: Hospital Outcome: **Response Options**: Discharge (recovered); Death related to or as complication of COVID-19; Death unrelated to COVID-19; Other (If OTHER) Please specify: Date of hospitalisation discharge:
	- Dates should be collected in following format - DD-MM-YYYY - The main difference between the different wards within a hospital is the nurse to patient ratio. Usually an Intensive Care Unit patient requires one to one nursing care, whilst a High Care Unit patient requires one nurse to every two patients. In contrast, on a general ward two qualified nurses often care for up to 30 patients between them. - Ending hospitalisation refers to the removal of a patient from any of the aforementioned units for reasons other than hospitalisation.
	(PREGNANT PARTICIPANTS ONLY) Signs and Symptoms at hospital admission: - Vaginal watery discharge - Vaginal bleeding - Headaches - Vision changes - Right upper quadrant (abdominal pain)

<table>
<tr><td></td><td>
- Decreased or no fetal movement
- Uterine Contractions
- Other
(PREGNANT PARTICIPANTS ONLY) Fetal Heart Rate at admission:
</td></tr>
<tr><td>Questions</td><td>
At ANY time during hospitalisation, did the patient receive/ undergo:
- (Pregnant participants only) Tocolysis; (Pregnant participants only) Induction of labour; Inotropes/vasopressors; Invasive ventilation; Non-invasive ventilation; Oxygen therapy; Prone Positioning; Renal replacement therapy (RRT) or dialysis; Other
Response Options: Yes; No
(If OTHER) Please specify:
</td></tr>
<tr><td>Notes</td><td>
- Interventions refer to extraordinary measures required to improve or maintain the health status of a participant during their hospitalisation.
- Intervention descriptions:
<table>
<tr><td>Intervention</td><td>Description</td></tr>
<tr><td>Inotropes/ vasopressors</td><td>Medications used to create vasoconstriction or increase cardiac contractility.</td></tr>
<tr><td>Invasive ventilation</td><td>A type of mechanical ventilation using endotracheal intubation.</td></tr>
<tr><td>Non-invasive ventilation</td><td>techniques for administering artificial respiration without the need for intratracheal intubation.</td></tr>
<tr><td>Oxygen therapy</td><td>Inhalation of oxygen aimed at restoring toward normal any pathophysiologic alterations of gas exchange in the cardiopulmonary system, as by the use of a respirator, nasal catheter, tent, chamber, or mask.</td></tr>
<tr><td>Prone Positioning</td><td>The posture of an individual lying face down.</td></tr>
<tr><td>RRT</td><td>Procedures which temporarily or permanently remedy insufficient cleansing of body fluids by the kidneys.</td></tr>
<tr><td>Dialysis</td><td>Therapy for the insufficient cleansing of the blood by the kidneys based on dialysis and including hemodialysis, peritoneal dialysis, and hemodiafiltration</td></tr>
</table>
</td></tr>
<tr><td>Questions</td><td>
At any time during hospitalisation did the participant experience any of the following complications:
- Acute kidney failure; Acute on Chronic Kidney Insufficiency; Ascites; Dyspnea; Hepatitis; Multiple organ dysfunction/failure; Pancreatitis; Pleural effusion; Pneumonia; Respiratory failure; Septic shock; Other
Response Options: Yes; No
(If Other) Please specify:
</td></tr>
</table>

<table>
<tr><td>Notes</td><td>
- Complications only include those conditions experienced during hospitalisation.
- Complications descriptions:
<table>
<tr><th>Complications</th><th>Descriptions</th></tr>
<tr><td>Acute kidney failure</td><td>Abrupt reduction in kidney function, as manifested by decreased urine production, and a rise in serum creatinine or blood urea nitrogen concentration.</td></tr>
<tr><td>Acute on Chronic Kidney Insufficiency</td><td>Conditions in which the kidneys perform below the normal level in the ability to remove wastes, concentrate urine, and maintain electrolyte balance; blood pressure; and calcium metabolism.</td></tr>
<tr><td>Ascites</td><td>Accumulation or retention of free fluid within the peritoneal cavity.</td></tr>
<tr><td>Dyspnea</td><td>Difficult or labored breathing.</td></tr>
<tr><td>Hepatitis</td><td>Inflammation of the liver.</td></tr>
<tr><td>Multiple organ dysfunction/ failure</td><td>A progressive condition usually characterized by combined failure of several organs such as the lungs, liver, kidney, along with some clotting mechanisms, usually postinjury or postoperative.</td></tr>
<tr><td>Pancreatitis</td><td>Inflammation of the pancreas.</td></tr>
<tr><td>Pleural effusion</td><td>Presence of fluid in the pleural cavity resulting from excessive transudation or exudation from the pleural surfaces.</td></tr>
<tr><td>Pneumonia</td><td>Infection of the lung often accompanied by inflammation.</td></tr>
<tr><td>Respiratory failure</td><td>Failure to adequately provide oxygen to cells of the body and to remove excess carbon dioxide from them.</td></tr>
<tr><td>Septic shock</td><td>Sepsis associated with hypotension or hypoperfusion despite adequate fluid resuscitation. perfusion abnormalities may include, lactic acidosis; oliguria; or acute alteration in mental status.</td></tr>
</table>
</td></tr>
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Protocol 11: Medication History

The protocol enables the collection of information related to the participant's ingestion of both concomitant medication as well as medication prescribed as a result of COVID-19 or MISC infection. Protocol 11 may be used alongside Protocol 12, or only ONE of these may be employed based on the study design.

Questions	Date of collection: Confirm whether the participant has used or been treated with any of the following medications (indicate most recent instance): **Response Options**: Today or yesterday; 2-7 days ago;

1-4 weeks ago;
1-12 months ago;
Over a year ago;
Never

Medication Type	Description & Examples
ACE-inhibitors	A class of drugs used for treatment of hypertension and heart failure. E.g. Captopril, Enalapril, Lisinopril, Benazepril, Quinapril
Allergy medications	Medications used to treat allergy symptoms. E.g. Chlorpheniramine, Cetirizine, Ketotifen, Pseudoephedrine, Budesonide
Androgen deprivation therapy	Medications used for treatment of prostate cancer. E.g. Leuprolide, Goserelin, Triptorelin, Bicalutamide, Nilutamide
Angiotensin II Receptor Blockers	Medications used for treatment of hypertension. E.g. Candesartan, Losartan, Telmisartan, Valsartan, Azilsartan
Antibiotics	Medications used to treat bacterial infections. E.g. Penicillin, Doxycycline, Cephalexin, Ciprofloxacin, Azithromycin.
Antifungal agents	Substances that destroy fungi by suppressing their ability to grow or reproduce. E.g. Clotrimazole, Miconazole, Griseofulvin, Amphotericin B, Nystatin.
Antimalarial agents	Agents used in the treatment of malaria. E.g. Artesunate, Artemether-lumefantrine, Chloroquine, Primaquine, Quinine.
Asthma medication	Medications used to open the airways and relieve asthma attacks. E.g. Salbutamol, Ipratropium, Theophylline, Corticosteroids (Budesonide).
Bile acids	Medications used to lower cholesterol to prevent heart attacks, stroke, and circulation problems. e.g.: Cholestyramine, Colestipol, Colesevelam.
Blood thinners	Agents that prevent blood clotting. E.g.: Dabigatran, Edoxaban, Heparin, Rivaroxaban, Warfarin
Experimental agents	Unofficial agents trialled for treatment of a specific condition.
Immune Globulin	Multi-subunit proteins used to treat autoimmune, infectious and idiopathic diseases E.g.: Asceniv, Bivigam, Cutaquig, Cuvitru, Anthrasil
Immuno-suppressive	Immunosuppressant drugs are used to treat autoimmune diseases and can be divided into classes including calcineurin

	<table><tr><td>medication</td><td>inhibitors, interleukin inhibitors, selective immunosuppressants and TNF alpha inhibitors.</td></tr><tr><td>Intravenous Fluids</td><td>Fluids administered intravenously to restore the volume and composition of the body fluids to normal with respect to water-electrolyte balance.</td></tr><tr><td>biologics" or "monoclonal antibodies"</td><td>Medication used to treat some types of cancer, cardiovascular disease, and autoimmune diseases E.g. Trastuzumab, Tituximab, Abciximab, Adalimumab, Dupixent</td></tr><tr><td>Non-influenza antiviral</td><td>Agents used in the prophylaxis or therapy of viral diseases like HIV, Hepatitis B and C E.g. Acyclovir, Zidovudine, Abacavir, Lamivudine, Entecavir</td></tr><tr><td>Non-steroidal anti-inflammatory drugs (NSAIDs)</td><td>Medicines that are used as anti-inflammatory, analgesic and antipyretic E.g. Aspirin, Mefenamic acid, Diclofenac, Naproxen, Ibuprofen</td></tr><tr><td>Oral Fluids</td><td>Fluids administered orally to restore the volume and composition of the body fluids to normal with respect to water-electrolyte balance e.g. ORT</td></tr><tr><td>Other pain/ fever relievers</td><td>Medications other than NSAIDs used to relieve pain and reduce fever. E.g. Acetaminophen, Nefopam, Narcotics (Morphine, Pethidine)</td></tr><tr><td>Steroids</td><td>Also called corticosteroids, are anti-inflammatory medicines used to treat a range of conditions. E.g. Prednisolone, Methylprednisolone, Beclometasone, Fluticasone, Hydrocortisone</td></tr><tr><td>Vitamin C</td><td>Used to treat vitamin C deficiency, scurvy, delayed wound and bone healing, urine acidification, and in general as an antioxidant.</td></tr><tr><td>Vitamin D</td><td>Used in the treatment of hypoparathyroidism, refractory rickets, and familial hypophosphatemia.</td></tr><tr><td>Other</td><td>NA</td></tr></table> (If Other) Please specify:
Notes	- Dates should be collected in following format - DD-MM-YYYY - Medication descriptions are provided in the above table. - If information related to broad classes of medication is unavailable, Protocol 12 may be employed.

Protocol 12: Medications (General)

The protocol enables the collection of information related to the participant's ingestion of concomitant medication as well as medication received during hospitalisation. Based on the study design, this Protocol can be used alongside or as alternative to Protocol 11.

Questions	Medication name: Medication Coded Name: Reason for medication: Start date: Ongoing? **Response Options**: Yes; No Stop date: Dose amount: Dose unit: **Response Options**: mg; ml; spray or puff; tablet; pill; softgel; capsule; application Dose frequency: **Response Options**: once per day (QD); twice a day (BID); three times a day (TID); four times a day (QID); nightly (NOCT); as needed (PRN) Route of administration: **Response Options**: Orally; Per rectum; Intravenous; Per vaginal; Inhaled; Intramuscularly; Nasogastric; Subcutaneously; Sublingually; Topical
Notes	- Participants should be asked to bring all their current medications with them at the time of their appointment. - For over-the-counter or self-prescribed medications (including vitamins and supplements), the details for medications consumed in the previous 2 weeks.

Protocol 13: Lab Tests

The protocol enables the recording of results from laboratory tests associated with the research participant. The protocol and all measurements included is optional and depends on the research objectives.

Questions	Blood Grouping Result Date: Blood Grouping Blood Type Rh factor
Notes	- Dates should be collected in following format - DD-MM-YYYY - All blood grouping test results should be collected from a qualified medical laboratory facility.
Questions	Haematology Result Date: Haematology: - White blood cell count Red blood cell count

	Platelets Lymphocytes Neutrophils Monocytes Eosinophils Basophils Haematocrit Hemoglobin Prothrombin Time ESR (Erythrocyte sedimentation rate)
Notes	- Dates should be collected in following format - DD-MM-YYYY - All Haematology results should be collected from a qualified medical laboratory facility.
Questions	Chemical Pathology Result Date: Chemical Pathology: - ACE2 Receptor (ACE2R) level Alkaline Phosphatase (ALP) ALT (Alanine amino transferase) Amylase AST (Aspartate amino transferase) Blood Glucose Blood Urea Nitrogen BNP (B-type Natriuretic Peptide) Cholesterol CRP (C-reactive protein) D-dimer Gamma-Glutamyl Transferase (GGT) High-density lipoprotein (HDL) IL-6 (Interleukin 6) Lactate LDH (Lactic acid dehydrogenase, Serum) Lipase Low-density lipoprotein (LDL) Pro-BNP Procalcitonin Potassium Serum ACE level Serum Albumin Serum Fibrogenin Serum Ferritin Serum Total Bilirubin Sodium Triglycerides

	Total Protein TROP I (Troponin-I) TROP T (Troponin T) Tumor necrosis factor - alpha
Notes	- Dates should be collected in following format - DD-MM-YYYY - All Chemical Pathology results should be collected from a qualified medical laboratory facility.

Abbreviations

ACE: Angiotensin-converting enzyme
ART: Antiretroviral therapy
CKD: Chronic Kidney Disease
COVID-19: Coronavirus Disease 2019
CT: Computed tomography
ECG: electrocardiogram
ELO: Ethnolinguistic Ontology
GFR: Glomerular filtration rate
HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
MIS-C: Multisystem inflammatory syndrome
PCR: Polymerase Chain Reaction
pro-BNP: proB-type Natriuretic Peptide
rRT-PCR: real-time Reverse Transcription Polymerase Chain Reaction
TB: Tuberculosis
CHD: Congenital Heart Disease
COPD: Chronic Obstructive Pulmonary Disease
CF: Cystic Fibrosis
CVD: Cardiovascular Disease
ORT: Oral Rehydration Therapy
NSAIDs: Non-steroidal anti-inflammatory drugs
SARS-COV-2: Severe acute respiratory syndrome coronavirus 2
RRT: Renal replacement therapy
ESR: Erythrocyte sedimentation rate
ALP: Alkaline Phosphatase
ALT: Alanine aminotransferase
AST: Aspartate aminotransferase
CRP : C-reactive protein
GGT: Gamma-Glutamyl Transferase GGT
HDL: High-density lipoprotein
IL-6: Interleukin 6
LDH: Lactic acid dehydrogenase
LDL: Low-density lipoprotein
TROP I: Troponin-I
TROP T: Troponin T

BNP: B-type Natriuretic Peptide

Administration

Mode of Administration

	Protocols																		
	A	B	C	D	E	F	1	2	3	4	5	6	7	8	9	10	11	12	13
Interview OR Self-administered questionnaire	X	X	X	X	X	X	X	X	X	X		X		X			X	X	
Clinical assessment		X								X	X		X		X	X			
Bioassay/Lab-based assessment												X							X

Life Stage

	Protocols																		
	A	B	C	D	E	F	1	2	3	4	5	6	7	8	9	10	11	12	13
Infancy (0 - 12 months)	X	X	X		X			X	X	X	X	X	X	X	X	X	X	X	X
Toddler (13 - 24 months)	X	X	X		X			X	X	X	X	X	X	X	X	X	X	X	X
Childhood (2-11 years)	X	X	X		X			X	X	X	X	X	X	X	X	X	X	X	X
Adolescence (12 - 18 years)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adult (18 and older)	X	X		X		X	X	X	X	X	X	X		X	X	X	X	X	X

Personnel and Training Required

Core Phenotypes

Protocols A to F may be implemented as either self-reported questionnaires or interviewer-administered questionnaires. If interviewer-administered, interviews should be conducted by

trained or study coordinators or data collectors who speak the native/local language of the target population.

COVID-19 & MIS-C Specific Phenotypes

It is recommended that Information from **Protocol 4 to 7 and 8 to 11** be recorded from hospital and(or) patient records. This suggests that this information needs to be collected and(or) confirmed by a trained and qualified healthcare professional, though **Protocols 4 and 11** may rely upon some self-reported participant data. Information recorded in **Protocol 13** needs to be gained from qualified medical laboratory facilities, with trained and qualified laboratory staff.

References

The COVID-19 module is based on and aligned with several existing standards, to facilitate data harmonisation. These resources are listed below:

1. Global Effort on COVID-19 (GECO) Health Research Phenotype Questionnaire.
2. Enhanced COVID-19 Notifiable Medical Conditions (NMC) Notification Form (SA)
3. PHA4GE SARS-CoV-2 Contextual Data Specification - Collection template
4. NSW Government COVID-19 case questionnaire
5. WHO Global COVID-19 Clinical Platform: Rapid core case report form
6. WHO Global COVID-19 Clinical Platform: Case Report Form for suspected cases of Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19
7. Enhanced MIS-C Notifiable Medical Conditions (NMC) Notification Form (SA)
8. Mayo Clinic Documentation

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Contact Us

For queries related to this standard and guideline, users can log a ticket to the Phenotypes Standards queue in the H3ABioNet Helpdesk. User feedback and improvements on the current module are welcome and encouraged. These can also be submitted through the Helpdesk, or on our GitHub Issues page.