

Operational framework for the conduct of the ENDIA study visits during the COVID-19 pandemic

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PPE = personal protective equipment.

Operational level: "Nickname"	Local/State/National Situational requirements	Description of procedures	PPE requirements
Level 7: "Frozen protocol"	 Stage 4 or higher lockdown: high level of epidemiological risk across large geographical areas Site laboratory shut-down via Government or institutional directive 	 Postage of study materials Self-collection of biospecimens (excluding blood) Storage in family home freezer until safe pick-up can be arranged No blood collection 	
Level 6: "Avon protocol"	 Stage 3 or 4 lockdown: high level of epidemiological risk across large geographical areas Site laboratory access available Essential travel permitted Household visitors prohibited Institutional restrictions on outpatient activities 	 Postage or drop-off of study materials Self-collection of biospecimens (excluding blood) Pick-up from family's doorstep without contact No blood collection 	Not applicable; Non-contact
Level 5/4: "Storm trooper protocol"	 Level 5: Applies to children with clinical indication for blood draw (e.g. antibody positive) where otherwise Level 6 restrictions would exist Eevel 4: Epidemiological risk linked with specific geographical areas (i.e. 'hot spots'), or family circumstances of increased risk Site laboratory access available Local travel permitted Household visitors permitted Institutional restrictions on outpatient activities 	 Level 5: Postage or drop-off of study materials Self-collection of biospecimens (excluding blood) Coordinator-assisted blood draw in the family home Contact time <15 minutes Level 4: Postage or drop-off of study materials Coordinator-assisted collection of biospecimens including blood in the family home Contact time >15 minutes 	P2/N95 mask with full face shield, long sleeved gown, gloves
Level 3: "Twilight protocol"	 Reduced epidemiological risk Laboratory access available Local travel permitted 	Postage or drop-off of study materials	Standard precautions



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	 Household visitors permitted Institutional restrictions on outpatient activities 	 Self-collection of biospecimens (excluding blood) Coordinator-assisted blood draw in the family home Contact time <15 minutes 	
Level 2: Standard pre- COVID home visit	 No epidemiological risk factors Site laboratory access available Unrestricted travel Household visitors permitted Institutional restrictions on outpatients activities 	 Coordinator-assisted collection of biospecimens including blood in the family home Contact time >15 minutes 	Standard precautions
Level 1: Standard pre- COVID clinic visit	 No epidemiological risk factors Site laboratory access available Unrestricted travel Outpatient clinics have resumed 	 Coordinator-assisted collection of biospecimens including blood at the clinical site Contact time >15 minutes 	Standard precautions