This form is designed to collect information on the Ethical and Regulatory barriers of delivering research in epidemic settings. Please complete one form per sample collection.

1. Centre Details

Clinical centre name and country:_____

Form completed by:_____

Date of form completion *(DD/MM/YYYY):* ____ /____ /_____

2. Specimen Details

Number of samples planned for testing by the site:_____samples

Origin of samples:

☐Collected at this centre
☐Collected at an external centre and transferred to this centre
☐Collected in the community and stored at this centre
☐Other (specify): _____

Why were the specimens collected:

☐Prospective collection for testing of nCoV
☐Prospective collection for another research study
☐Prospective collection for clinical care
☐Retrospective identification of samples in storage
☐Other (specify): _____

Informed Consent was obtained to *(check all that apply)*:

☐Take samples for research purposes
☐Test samples for nCoV
☐Store samples for use in future research
☐Informed consent was not obtained
☐A waiver of informed consent was approved by the relevant ethical committee
☐Other (specify): _____

3. Approval / Authorization

Was the study approved by one or more ethical committees or regulatory agency? ☐Yes ☐No

If yes, please complete the following: *(Total amount of time to approval should include completion of forms by researchers, awaiting the meeting, correspondence, revisions and receipt of approval letter)*

Institution/Agency	Type of Committee/Agency	Approval date (DD/MM/YYYY)	Total amount of time to approval
1.	☐Ethical Committee ☐Regulatory Agency ☐Ethical and Regulatory	☐Not approved ____ /____ /_____	☐days ☐weeks
2.	☐Ethical Committee ☐Regulatory Agency ☐Ethical and Regulatory	☐Not approved ____ /____ /_____	☐days ☐weeks
3.	☐Ethical Committee ☐Regulatory Agency ☐Ethical and Regulatory	☐Not approved ____ /____ /_____	☐days ☐weeks
4.	☐Ethical Committee ☐Regulatory Agency ☐Ethical and Regulatory	☐Not approved ____ /____ /_____	☐days ☐weeks

4. Issues

Please detail any issues that arose with respect to access to samples, ethical approval of use of samples or regulatory authorisation to test the samples. Details of the issue and the resolution should be included. Please upload copies of any relevant correspondence to the documents section of the online database entry system.

Committee / Agency 1._____

Committee / Agency 2._____

Committee / Agency 3._____

Committee / Agency 4._____

Any additional feedback on ethical and regulatory barriers encountered would be appreciated:_____