

Generic protocol

A prospective cohort study investigating maternal, pregnancy and neonatal outcomes for women and neonates infected with SARS-CoV-2

Version 2.6

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Contact: hrp_covid19pregnancycohort@who.int

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: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations>

COVID-19 investigations and study protocols [available](#) 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)

7. Longitudinal cohort study on pregnancy & COVID-19: maternal and neonatal transmission protocol

Please contact hrp_covid19pregnancycohort@who.int for questions related to the maternal and neonatal transmission protocol and earlyinvestigations-2019-nCoV@who.int for questions related to other early investigation protocols.

All WHO protocols for COVID-19 are available on the [WHO website](#) together with the technical guidance documents.

This protocol may be subject to revisions, pending research governance processes¹.

Responsible officers:

Nathalie Broutet (Coordination of partners and protocol)

Anna Thorson (Responsible officer)

Coordination of Implementation:

Ibukun Abejirinde (Focal point, Implementation)

Christine Godwin (Focal point, External partners and working groups)

Pregnancy cohort Implementation team

Edna Kara (Implementation, Latin America)

Soe Soe Thwin (Manager, Data platform and Statistics)

Mohamed Ali (Technical support, Statistics)

Ndema Habib (Technical support, Statistics)

Daniel Giordano (Technical support, Data platform)

For questions related to implementation or other aspects of pregnancy related SARS-CoV-2 research, please send an email to hrp_covid19pregnancycohort@who.int

¹ Version 2.2 of this protocol and its accompanying appendix dated 14 August 2020 have been approved by the WHO Ethical Review Committee. This updated version (v.2.6 dated 2 December 2020) will undergo an amendment review by the WHO Ethical Review Committee based on revised sample size calculations, including information on the pooled analysis (pp. 10–13, Appendix B), revision of the case report forms (CRFs) (Appendix B), inclusion of draft guidelines on mother-to-child transmission (MTCT) (Appendices I–L) and general revisions to improve coherence and content alignment.

Contents

Protocol summary.....	6
List of abbreviations.....	7
Preamble	8
1 Introduction.....	9
2 Research plan	9
3 Problem statement, aims and objectives	10
3.1 Definitions	11
3.2 Outcomes and objectives.....	11
4 Required elements of protocol	12
5 Methods	12
5.1 Study design	12
5.1.1 Objectives 1, 3, 4 and secondary objectives	12
5.1.2 Specific study design for Objective 2	16
5.2 Study participants and sampling	16
5.2.1 Study population.....	16
5.2.2 Exposure status.....	16
5.3 Recruitment.....	17
5.4 Sample size calculation	17
5.5 Methods of data collection	19
5.5.1 Schedule of the cohort.....	19
5.6 Data collection and management	19
5.6.1 Questionnaire/CRF and biological specimen	19
5.6.2 Specimen collection and laboratory investigation.....	21
5.6.3 Laboratory procedures	23
5.7 Data analysis.....	23
5.8 Data management and data access.....	24
5.8.1 Procedures for ensuring confidentiality	24
5.8.2 Data management	25
5.8.3 Dissemination and utilisation of results, including publication plans.....	26
5.8.4 Contributions to gender equality, equity and the human rights agenda	26
5.8.5 Research capacity strengthening	26
5.8.6 Environmental considerations	27
5.9 Ethical considerations.....	27
5.9.1 Informed consent.....	27
5.9.2 Incentives to participate and compensation	30
5.9.3 Policy on incidental findings	30
5.9.4 Benefits and risks for study subjects.....	31
5.9.5 Biobank guidance.....	32
6 References.....	33
7 Acknowledgements.....	35
Appendix A: Description of investigation and informed consent template	36
Appendix A1: Consent to the use of biological samples	44
Appendix B: Sample size estimates for individual sites and standardized questionnaires/CRFs.....	46
Sample size for site-specific and pooled data	46
Standardised questionnaires/CRFs	58
Appendix C: Biological sampling algorithm.....	110
Appendix D: Options for variations in study design	112
Appendix E: Standardized questionnaire for non-pregnant women with SARS-CoV-2.....	116

Appendix F: Specimen storage, preservation and shipment.....	118
Appendix G: Sample tables for study outcomes	119
Appendix H: Biobank guidance	122
Appendix I: Draft criteria for defining in utero transmission of SARS-CoV-2	124
Appendix J: Draft criteria for defining intrapartum and postnatal transmission of SARS-CoV-2...	129
Peripartum transmission	129
Postnatal horizontal transmission	132
Appendix K: Potential testing of live birth for determination of infection timing.....	135
Appendix L: Potential samples to test for timing of SARS-COV-2 perinatal infection	136
Appendix references	138

Protocol summary

To better understand how severe acute respiratory coronavirus-2 (SARS-CoV-2) infection impacts outcomes in women and their neonates during pregnancy and the postpartum period, the World Health Organization (WHO) has developed a standardized research protocol for the investigation of coronavirus disease 2019 (COVID-19) in pregnant women. The protocol addresses key research questions, facilitates systematic and harmonized collection of data and biological specimens, and allows for data comparison and aggregation across different locations while minimizing potential biases. The protocol is designed to be adapted as needed in each study site based on resource availability and local circumstances.

This protocol outlines a prospective cohort study investigating the outcomes of pregnant or recently pregnant women infected with SARS-CoV-2 (exposed) compared to pregnant or recently pregnant women not infected with SARS-CoV-2 during pregnancy (unexposed). The purpose of this study is to determine if SARS-CoV-2 infection during pregnancy increases the risk of adverse pregnancy, postpartum or neonatal outcomes. Additionally, the study characterizes the clinical spectrum of COVID-19 in pregnant women, quantify (if any) the rate of in utero/intrapartum/postnatal transmission, determine the incidence of detectable SARS-CoV-2 RNA in pregnancy-related fluids (i.e. amniotic fluid), breast milk and tissues, and follow clinical outcomes of women and their newborns up to 6 weeks after childbirth.

It is expected that findings from studies implementing this protocol will be published, widely disseminated and used to develop recommendations on the surveillance, management and counselling of women during and after pregnancy, as well as their babies, in the context of the COVID-19 pandemic. Findings related to the implementation of this study protocol will help to inform public health measures, infectious disease and prevention measures, and future research protocols.

List of abbreviations

ARDS	acute respiratory distress syndrome
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	coronavirus disease 2019
CRF	case report form
FGR	fetal growth restriction
GCP	good clinical practice
GDRP	general data protection regulation
HRP	UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
IDMC	Independent Data Monitoring Committee
IPC	infection prevention and control
IRB	institutional review board
IUT	intrauterine transmission
LFU	loss to follow-up
LMICs	Low- and middle-income countries
MERS	Middle East respiratory syndrome
MTA	material transfer agreement
MTCT	mother-to-child transmission
NICU	neonatal intensive care unit
RDT	rapid diagnostic test
RT-PCR	reverse transcriptase polymerase chain reaction
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
TORCH	toxoplasmosis, rubella, cytomegalovirus, herpes simplex
WHO	World Health Organization
WG	working group

Preamble

This protocol is one of the WHO protocols for COVID-19 designed to enable the rapid and systematic collection of data in a format that facilitates comparison across different settings. All WHO investigation protocols for COVID-19 are available on the [WHO website](#).

Any partner who wishes to use this protocol can do so freely and without charge or obligations. We ask implementing study sites to kindly inform the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)/World Health Organization (WHO) about their implementation of this protocol and to provide a contact point. Please share your information with hrp_covid19pregnancycohort@who.int

Implementing partners can opt to manage data onsite or through the central HRP repository subject to local circumstances. A pooled analysis bringing together all consenting and contributing sites will be discussed with sites implementing the study. Sites that agree to pool data under the coordination of WHO/HRP will have the option to independently publish their own data. The analysis of the pooled data will be made available and widely disseminated in collaboration with all contributing sites. All partners will retain control of their site data, regardless of whether or not this data is included in pooled or aggregated analyses.

All sites wishing to participate are invited to do so; however, WHO/HRP provides no guaranteed support for study implementation. Technical, financial or capacity limitations may be present. However, since this protocol proposes a study design that can be adapted to allow for smaller studies (see Appendix D for proposed methodologies), studies that follow the proposed study design may be pooled/aggregated in order to achieve an overall pooled sample size with sufficient statistical power to answer the primary research questions.

It is important to note that this protocol is designed to describe the core data variables in order to answer the key research questions and primary objectives outlined in the protocol. As such, the implementation of this study may include additional objectives or study components, as determined by each implementing site.

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.

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_24228

