Pregnancy CRF (CRF-P)

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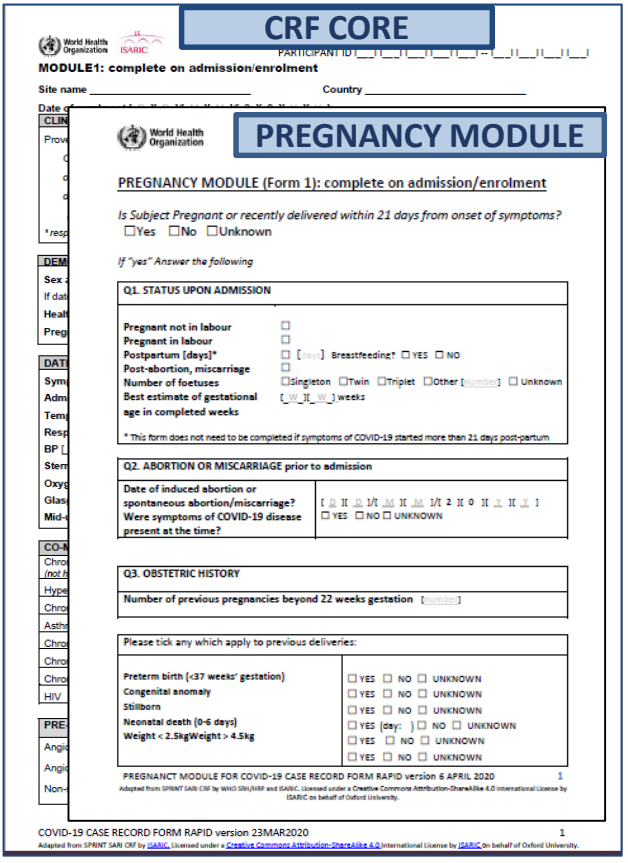
Standardized clinical case report form: Pregnancy CRF



CASE REPORT FORM (CRF)

Core CRF + Pregnancy module= PREGNANCY CRF (CRF-P)

Pregnancy CRF has 3 modules:

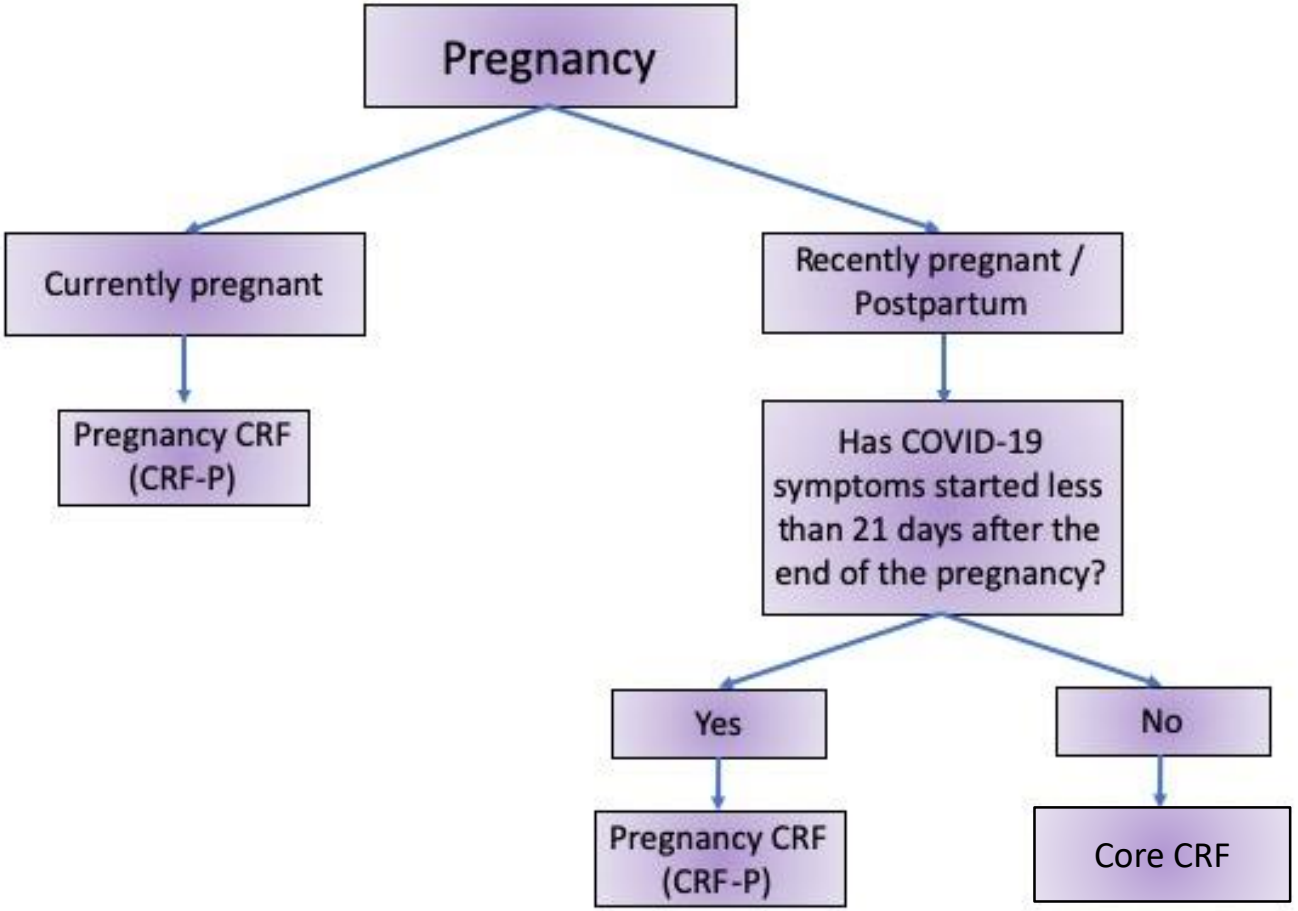
Module 1 : admission

Module 2 : daily follow up

Module 3 : pregnancy outcomes, discharge, death, transfer

Data may be collected **prospectively or retrospectively** through examination and review of medical records, and can be entered in the **WHO COVID-19 Clinical Platform**

Pregnancy CRF: Flow diagram



CRF-P Module 1

World Health Organization

PREGNANCY MODULE 1. Complete on hospital admission (within 24 hrs from hospital admission)

Facility name: _____ **Country:** _____

Date of enrolment: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

1a. CLINICAL INCLUSION CRITERIA

Proven or suspected infection with pathogen of public health interest ☐Yes ☐No

One or more	A history of self-reported feverishness or measured fever of ≥38°C	☐Yes	☐No
of these	Cough	☐Yes	☐No
during this	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes	☐No
illness	Clinical suspicion of ARI despite not meeting criteria above	☐Yes	☐No

** Respiratory rate ≥ 50 breaths/min for < 1 year; ≥ 40 for 1–4 years; ≥ 30 for 5–12 years; ≥ 20 for ≥ 13 years*

1b. DEMOGRAPHICS

Sex at birth ☐Male ☐Female ☐Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is unknown, record: **Age** [___][___][___] **years** OR [_][_] **months**

Health care worker? ☐Yes ☐No ☐Unknown **Laboratory worker?** ☐Yes ☐No ☐Unknown

Pregnant?* ☐Yes ☐No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [___][_]weeks

If currently pregnant or recently pregnant (delivery within 21 days of symptom onset), complete all sections

1c. DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Admission date at this facility [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Temperature [ ][ ].[ ]°C **Heart rate** [ ][ ][ ]beats/min

Module 1 continued

1j. PREGNANCY STATUS UPON ADMISSION	
Pregnant not in labour	☐
Pregnant in labour	☐
Postpartum [days]*	☐ [days] Breastfeeding? ☐Yes ☐No
Post-abortion/miscarriage	☐
Number of foetuses	☐Singleton ☐Twin ☐Triplet ☐Other [number] ☐Unknown
Best estimate of gestational age in completed weeks	[_W_][_W_] weeks

Module 1

1k. ABORTION OR MISCARRIAGE *(prior to admission)*	
Date of induced abortion or spontaneous abortion/miscarriage?	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Were symptoms of COVID-19 disease present at the time?	☐Yes ☐No ☐Unknown

1l. OBSTETRIC HISTORY
Number of previous pregnancies beyond 22 weeks gestation [number]
Number of previous vaginal deliveries [number]
Number of previous cesarean deliveries [number]

1m. Please tick any which apply to previous deliveries:	
Preterm birth (< 37 weeks' gestation)	☐Yes ☐No ☐Unknown
Congenital anomaly	☐Yes ☐No ☐Unknown
Stillborn	☐Yes ☐No ☐Unknown
Neonatal death (0–6 days)	☐Yes [day:] ☐No ☐Unknown
Weight < 2.5 kg	☐Yes ☐No ☐Unknown
Weight > 4.5 kg	☐Yes ☐No ☐Unknown

Module 1 continued

1n. ALCOHOL, DRUGS – RISK FACTORS DURING THIS PREGNANCY	
Alcohol consumption	☐Yes ☐No ☐Unknown
Illicit/recreational drug use	☐Yes ☐No ☐Unknown

1o. MEDICATIONS DURING THIS PREGNANCY *(Prior to onset of current illness episode)*		
Fever or pain treatment	**Acetaminophen/paracetamol**	☐Yes ☐No ☐Unknown
	NSAID/s	☐Yes ☐No ☐Unknown
	Other/s (specify): [ ]	
Anticonvulsants	☐Yes ☐No ☐Unknown **If yes, specify generic name:** [ ]	
Anti-nausea	☐Yes ☐No ☐Unknown **If yes, specify generic name:** [ ]	
Prenatal vitamins and micronutrients	☐Yes ☐No ☐Unknown **If yes, specify generic name:** [ ]	
Antivirals	☐Yes ☐No ☐Unknown **If yes, specify generic name:** [ ]	
Antibiotics	☐Yes ☐No ☐Unknown **If yes, specify generic name:** [ ]	

Module 1

1p. ADMISSION SIGNS AND SYMPTOMS			
Vaginal watery discharge	☐Yes	☐No	☐Unknown
Vaginal bleeding	☐Yes	☐No	☐Unknown
Headaches	☐Yes	☐No	☐Unknown
Vision changes	☐Yes	☐No	☐Unknown
Right upper quadrant (abdominal) pain	☐Yes	☐No	☐Unknown
Decreased or no fetal movement	☐Yes	☐No	☐Unknown
Uterine contractions	☐Yes	☐No	☐Unknown

1q. FETAL HEART RATE *(first available data at presentation/admission)*	
Fetal heart rate	**(FHR):** [_ _][_ _][_ _] beats/min

CRF-P Module 2

2e. SUPPORTIVE CARE At any time during this 24-hour hospital day, did the patient receive:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown

Date of ICU/HDU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown

ICU/HDU discharge date [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Not discharged yet ☐Unknown

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all below:

O_2 flow: ☐ 1–5 L/min ☐ 6–10 L/min ☐ 11–15 L/min ☐ > 15 L/min ☐Unknown

Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown

Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown

Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐Yes ☐No ☐Unknown

Invasive ventilation (any)? ☐Yes ☐No ☐Unknown **If yes, what were the following values closest to 08:00:** PEEP (cm H_2O) _____; FiO_2 (%) _____; Plateau pressure (cm H_2O) _____; $PaCO_2$ _____; PaO_2_____

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown

Prone position? ☐Yes ☐No ☐Unknown

Inotropes/vasopressors? ☐Yes ☐No ☐Unknown

Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

2f. FETAL HEART RATE	
Fetal heart rate (record most abnormal value between 00:00 to 24:00)	**(FHR):** [_ _][_ _][_ _] beats/min

2g. TREATMENT DURING HOSPITALIZATION At ANY time during hospitalization, did the patient receive/undergo:	
Tocolysis	☐Yes ☐No ☐Unknown
Induction of labour	☐Yes ☐No ☐Unknown
Blood transfusion	☐Yes ☐No ☐Unknown

CRF-P Module 3

3f. DELIVERY, PREGNANCY AND MATERNAL OUTCOMES	
Delivery during adr	☐Yes ☐No

3g. PREGNANCY STATUS AT DISCHARGE	
Pregnancy outcome	☐Undelivered

3i. NEONATAL OUTCOMES	
Date of birth [DD/MM/YYYY] **Time of birth** [e.g. 14:21]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] [____:____]
Participant ID of the mother:	[___][___][___][___][___]-- [___][___][___][___] – [__Single digit Baby ID_]* *Complete one form per neonate
COVID-19 lab test of foetus or neonate	☐Performed ☐Not performed ☐Unknown If yes: [_sample collected__] [_test description__][_date of collection__] [_____result_____]
Apgar score at 5 minutes	Score: [___][___]
Gestational age	Weeks: [___][___] Days: [_____]
Birth weight	Grams: [___][___][___][___]
Respiratory distress syndrome	☐Yes ☐No ☐Unknown

Neonatal outcome	☐Discharged healthy ☐Discharged with complications/sequelae Details: [_____] ☐Clinical referral to specialist ward /other hospital Details: [_____] ☐Death Date of death: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] ☐Unknown

Module 3

Sections 3f–3i (to be completed if delivery happened within 21 days of symptom onset)

3f. DELIVERY, PREGNANCY AND MATERNAL OUTCOMES				
Delivery during admission	☐Yes ☐No			
Delivery date	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]			
Mode of delivery	☐ Vaginal delivery ☐ Caesarean section			
Onset of labour	☐ Spontaneous ☐ Induced ☐ Cesarean section before labour ☐ Unknown			
Fetal presentation at delivery	☐ Cephalic ☐ Transverse ☐ Breech			
Amniotic fluid at delivery	☐ Clear ☐ Meconium stained ☐ Unknown			
Other maternal outcomes/pregnancy complications	Gestational diabetes	☐Yes	☐No	☐Unknown
	Gestational hypertension	☐Yes	☐No	☐Unknown
	Anaemia (Hb < 11 g/dL)	☐Yes	☐No	☐Unknown
	Hyperemesis	☐Yes	☐No	☐Unknown
	Intrauterine growth restriction	☐Yes	☐No	☐Unknown
	Placental previa/accreta/percreta	☐Yes	☐No	☐Unknown
	Bacterial infection prior to hospital visit	☐Yes	☐No	☐Unknown
	Pre-eclampsia/eclampsia	☐Yes	☐No	☐Unknown
	Placental abruption	☐Yes	☐No	☐Unknown
	Preterm contractions	☐Yes	☐No	☐Unknown
	Preterm labour	☐Yes	☐No	☐Unknown
	Preterm rupture of membranes	☐Yes	☐No	☐Unknown
	Early or midterm miscarriage	☐Yes	☐No	☐Unknown
	Haemorrhage	☐Yes	☐No	☐Unknown
	If haemorrhage, which type:	☐ **Antepartum/intrapartum** ☐ **Postpartum haemorrhage** ☐ Abortion-related		
	Embolic disease	☐Yes	☐No	☐Unknown
	Anesthetic complication	☐Yes	☐No	☐Unknown

Module 3

3g. PREGNANCY STATUS AT DISCHARGE	
Pregnancy outcome	☐Undelivered ☐Spontaneous abortion ☐Induced abortion ☐Missed abortion

3h. SAMPLE COLLECTION				
Any sampling conducted? If so, please describe the test and the results	☐Amniotic fluid	[test description]	[date of collection]	[result]
	☐Placenta	[test description]	[date of collection]	[result]
	☐Cord blood	[test description]	[date of collection]	[result]
	☐Vaginal swab	[test description]	[date of collection]	[result]
	☐Faeces/rectal swab	[test description]	[date of collection]	[result]
	☐Pregnancy tissue in the case of fetal demise/induced abortion	[test description]	[date of collection]	[result]
	☐Breastmilk	[test description]	[date of collection]	[result]

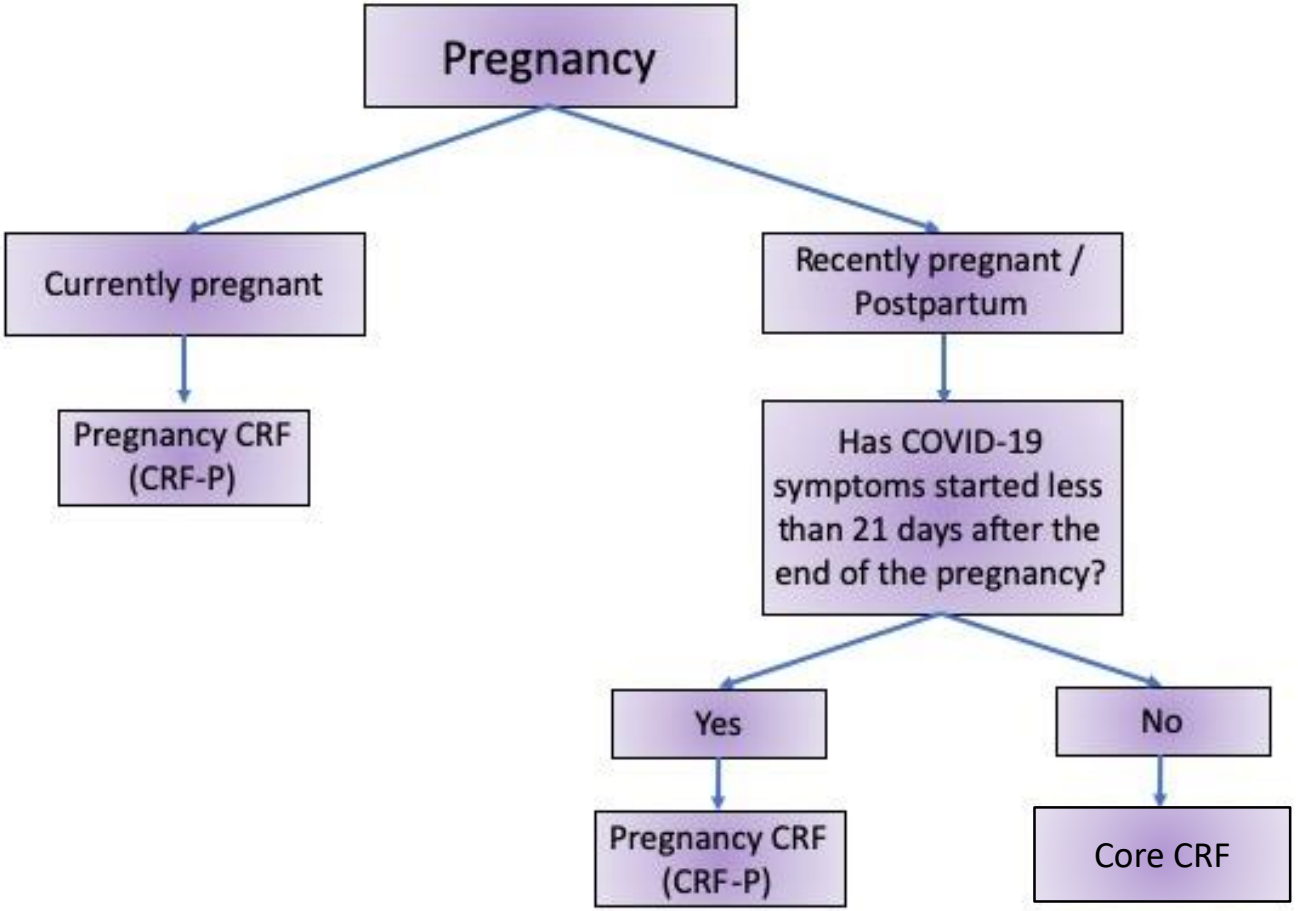
Module 3

3i. NEONATAL OUTCOMES	
Date of birth [DD/MM/YYYY] **Time of birth** [e.g. 14:21]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] [____:____]
Participant ID of the mother:	[___][___][___][___][___]– [___][___][___][___] – [_Single digit Baby ID_]* *Complete one form per neonate
COVID-19 lab test of foetus or neonate	☐Performed ☐Not performed ☐Unknown If yes: [_sample collected__] [_test description__][_date of collection__] [_____result_____]
Apgar score at 5 minutes	Score: [___][___]
Gestational age	Weeks: [___][___] Days: [_____]
Birth weight	Grams: [___][___][___][___]
Respiratory distress syndrome	☐Yes ☐No ☐Unknown

Neonatal outcome	☐Discharged healthy ☐Discharged with complications/sequelae Details: [_____] ☐Clinical referral to specialist ward /other hospital Details: [_____] ☐Death Date of death: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] ☐Unknown

If neonate died, primary cause of death	☐Preterm/low birth weight ☐Birth asphyxia ☐Infection ☐Birth trauma ☐Congenital/birth defects ☐Other ☐Unknown
Any congenital anomalies	☐Neural tube defects ☐Microcephaly ☐Congenital malformations of ear ☐Congenital heart defects ☐Orofacial clefts ☐Congenital malformations of digestive system ☐Congenital malformations of genital organs ☐Abdominal wall defects ☐Chromosomal abnormalities ☐Reduction defects of upper and lower limbs ☐Talipes equinovarus/clubfoot

CRF-P


Pregnancy
Currently pregnant
Recently pregnant / Postpartum
Pregnancy CRF (CRF-P)
Has COVID-19 symptoms started less than 21 days after the end of the pregnancy?
Yes
No
Pregnancy CRF (CRF-P)
Core CRF