GOVERNMENT OF ASSAM
HEALTH & FAMILY WELFARE DEPARTMENT
DISPUR ::: GUWAHATI

ORDERS BY THE GOVERNOR OF ASSAM
NOTIFICATION

Dated Dispur the 2nd July 2020

No.HLA.274/2020/33: The Health & Family Welfare Department, Government of Assam hereby notifies the following in connection with the medical management of COVID-19 patients in Assam :-

1. Treatment Protocol for COVID-19 patients in Assam (Annexure-I).
2. Treatment Algorithm for COVID-19 (Anneure-II).
3. Protocol for use of convalescent plasma for treatment of patients with COVID-19 infection in Medical College and Hospitals of Assam. (Annexure-III)

This notification comes into force with immediate effect.

(Samir K. Sinha, IAS)
Principal Secretary to the Govt. of Assam,
Health & Family Welfare Department

Memo No. HLA.274/2020/33-A Dated Dispur the 2nd July 2020

Copy to:

1) The Commissioner & Secretary to the Govt. of Assam, Health & Family Welfare Department.
2) Special Secretary, Health & Family Welfare Department.
3) Mission Director, National Health Mission, Assam, Guwahati.
4) The Addl. Secretary to the Govt. of Assam, Health & Family Welfare Department, Dispur, Guwahati.
5) The Deputy Commissioner (all districts) cum Chairman, District Registering Authority under Clinical Establishments (Registration and Regulation) Act, 2010.
6) The Director of Medical Education, Assam, Guwahati for necessary action.
7) The Director of AYUSH, Assam, Guwahati for necessary action.
8) The Director of Health Services– Cum – Member Secretary, Assam State Council for Clinical Establishments, Assam for necessary action. He is requested to forward this notification to all concerned including clinical establishments in the private sector.
9) The Director of Health Services (F.W), Assam, Hengrabari, Guwahati.

10) Principal cum Chief Superintendent/ Superintendent, Medical College & Hospital, GMCH, Guwahati / SMCH, Silchar / AMCH, Dibrugarh / FAAMCH, Barpeta / TMCH, Tezpur / JMCH, Jorhat/ DMC, Diphu for necessary action.
11) Addl. Director of Health Services, Assam–cum- State Nodal Officer for Clinical Establishment, Hengrabari, Guwahati.
12) The Joint Director of Health Services (all districts) cum Convener, District Registering Authority under Clinical Establishments (Registration and Regulation) Act, 2010,
13) P.S. to Hon'ble Chief Minister, Assam, Dispur.
14) P.S. to Hon'ble Minister, Health & Family Welfare, Assam.
15) P.S. to Hon'ble Minister of State, Health & Family Welfare, Assam.
16) P.S. to Chief Secretary, Assam, Dispur.
17) Any Other concerned.

By order etc.,

Deputy Secretary to the Govt. of Assam
Health & Family Welfare Department

ANNEXURE-I

TREATMENT PROTOCOL FOR COVID-19 PATIENTS IN ASSAM

A. MANAGEMENT OF ASYMPTOMATIC COVID-19 POSITIVE

Institutional Isolation for a maximum period of 14 days

1. Place the patient in a well-ventilated single room
2. Limit the movement of the patient and minimize shared space. Ensure that shared spaces (e.g. bathroom) are well ventilated
3. Visitors should not be allowed until the patient is discharged
4. Perform hand hygiene after any type of contact with other patients or their immediate environment.
5. To contain respiratory secretions, a medical mask should be provided to the patient and changed daily.
6. Use dedicated linen and eating utensils for the patient
7. Strict regular surface cleaning to be maintained
8. If the patient develops symptoms he/she is to be transferred to a Dedicated COVID hospital
9. Released from institutional isolation (CCC) as per discharge protocol.
10. After discharge from institutional isolation, they are to be advised home quarantine with following instructions:

    - Continue 14 days of strict home quarantine with self monitoring of symptoms
    - Wear a triple layered surgical mask
    - Live in a single room with good ventilation
    - Avoid close contact with family members
    - Eat separately
    - Keep hands clean and avoid outdoor activities

NB: It is recommended that discharged patients should have follow up visits in the 2nd and 4th weeks

MANAGEMENT OF COVID-19 SYMPTOMATIC PATIENTS

B. MANAGEMENT OF MILD CASES

1. Mild cases are those with low grade fever/cough/malaise/rhinorrhoea/sore throat WITHOUT any shortness of breath
2. Admission in COVID care centers (CCC)
3. Contact and droplet precautions, strict hand hygiene
4. Symptomatic treatment:
    a. Paracetamol, Cough syrup, Gargle with warm saline
    b. Tab. Zinc 50 mg/day
    c. Tab. Vitamin-C 500 mg/twice daily
    d. Tab. Vitamin-D_3 60k once weekly
    e. Tab. Famotidine 20mg BD
5. Antibiotics: Azithromycin 500 mg daily for 5 days or Amoxyclav (500+125) mg 8 hourly for 5 days.
6. Consider Favipiravir in selected cases.
7. Discharge as per protocol
8. Advice after discharge:
    - Continue 14 days of home quarantine with self monitoring of symptoms
    - Wear a triple layered surgical mask
    - Live in a single room with good ventilation
    - Avoid close contact with family members
    - Eat separately
    - Keep hands clean and avoid outdoor activities

NB: It is recommended that discharged patients should have follow up visits at 2nd and 4th weeks

c. MANAGEMENT OF HOSPITALIZED CASES (Moderate Cass)

Indication of Hospitalization

- Respiratory distress
- Respiratory Rate >24/min
- Spo2 <94% in Room Air

General Measures:

1. Symptomatic treatment
   a. Paracetamol, Cough syrup, Gargle with warm saline
   b. Tab. Zinc 50 mg/day
   c. Tab. Vitamin-C 500 mg/twice daily
   d. Tab. Vitamin-D 60 weekly
   e. Tab. Famotidine 20mg BD

2. Antibiotics as per clinician's discretion (to cover community acquired pneumonia including atypical pneumonia)
   a. Inj. Pipercilin+ Tezobactum 4.5mg IV 8 hourly (Modify doses according to creatinine clearance)
3. Thrombo-prophylaxis
   - All hospitalized patients should be started on prophylactic LMWH (e.g., Enoxaparin 1mg/kg per day Subcutaneously)/ unfractionated heparin if not contraindicated, and no high risk factors for bleeding are present
4. Maintain euvolemia , promote oral fluids, avoid IV fluids unless indicated
5. Corticosteroids:
   a. Dexamethasone 6mg Oral/IV OD for 5 to 10 days

   OR

   b. Methylprednisolone 250 to 500 mg IV OD for 5 days

6. Prone positioning in COVID-19

- Awake proning should only be considered if patient:
  - Is able to communicate and co-operate with the procedure
  - Is able to rotate to front and adjust position independently
  - Has no anticipated airway issue
- If patients fulfils criteria for proning, ask the patient to switch positions every 30 min to 2 hours ,while looking for improvement in oxygenation, as follows:

- Lying on right side
- Sitting up (30-60 degrees) by adjusting head of the bed
- Lying on left side
- Lying prone again

7. Anti-Viral: If oxygen requirement is increasing start REMDESIVIR

   Loading doses 200 mg IV over one hours followed by 100 mg IV daily for 5 days. if patients require mechanical ventilation doses should be extended to 10 days.

   REMDESIVIR should not be started in following groups of patients

   a. AST/ALT > 5 times of ULN
   b. eGFR < 30 ml/Min
   c. Pregnancy and lactating mothers
   d. Known to allergy to Remdesivir

8. If available consider Convalescent plasma : Infuse 200ml state followed by 200 ml after 24 hours if required. (prefer second doses from different donor).(after due consent) Refer to annexure 1 for details on CPT

9. Clinical assessment to identify those patients who require treatment as severe disease (see definition of Severe Disease)

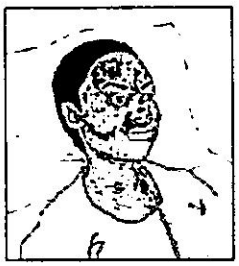
   - Tachyonoea
     (Excessive inspiratory efforts (requiring accessory muscles of respiration, large volume tidal breaths, air hunger)
   - Tachycardia
   - Shallow breathing
   - Increasing Oxygen requirement to maintain SPO2>94%
   - Impaired sensorium
   - Fall of Blood pressure

- Laboratory:
  - Routine: CBC with differentials, AST, ALT, Alk Phosphatase, Creatinine, RBS
  - Predictive and prognostic markers: CRP, LDH, Ferritin, D-Dimer, Troponin I , Procalcitonin, IL-6 level

Management of patients with hypoxemia and low Work of Breathing

10.Oxygen therapy

How to deliver increasing oxygen



Place prongs inside the nostril. Hook tubing behind ears. Flow rates higher than 5 L will dry mucous membranes.

→ Start oxygen at 5 L/min
→ Use nasal prongs
→ Assess response

If increasing respiratory distress or $SpO_2 < 90\%$*

Secure mask firmly on face over nose and mouth. Pull strap over head.

→ Use face mask
→ Increase oxygen to 6–10 L/min
→ Assess response

If increasing respiratory distress or $SpO_2 < 90\%$*

Make sure bag is full to deliver highest oxygen concentration. An empty bag is dangerous.

→ Use face mask with reservoir
→ Increase oxygen to 10–15 L/min
→ Make sure bag inflates
→ Call for help from district clinician
→ Assess response

If increasing respiratory distress or $SpO_2 < 90\%$*, transfer to a hospital with available invasive mechanical ventilator possible

High Flow Nasal Cannula (HFNC) if avalable

Apply Non Invasive Ventilation (NIV)

SEVERE CASES: (ICU CARE): if any two of the following is present:

a. Severe respiratory distress
b. Respiratory Rate >30/min
c. SpO2 <90 % in room air
d. Altered sensorium
e. Blood pressure < 90/60 mm Hg
f. New onset/ worsening organ dysfunction

1. All treatment modalities for moderate disease to be instituted
2. If not responding, monitor IL-6 level, if Il-6>5 times upper limit of normal, consider TOCILIZUMAB
   Contraindicatios:
   Platelet count<50k
   Dosage: 8mg/kg, (should not be more than 800mg) in 100 ml normal saline slowly infuse over 1 hour. May be repeated after 12-24 hours if indicated
3. Non invasive ventilation
   - If the target SPO2 is not achieved/maintained with the above mentioned devices, NIV may be given (via helmet interface is preferred)
   - Use of NIV requires intensive monitoring for any increase in work of breathing and hemodynamic instability
   - In NIV start with IPAP 8 and EPAP 5 to 6 , and gradually increased pressure according to patient requirement.
   - When improving titrate the NIV pressure gradually by decreasing 2 of both IPAP and EPAP
   - Note:
     - NIV is associated with high failure rates, particularly in de-novo respiratory failure.
     - NIV without helmet interface is associated with greater risks of aerosolisation leading to higher exposure of health care workers
     - Placing a Surgical mask over Nasal mask may help in reducing dispersion

11.Prone positioning in COVID-19 (Awake proning prior to intubation)

- Awake proning should only be considered if patient:
  - Is able to communicate and co-operate with the procedure
  - Is able to rotate to front and adjust position independently
  - Has no anticipated airway issue

- If patients fulfils criteria for proning, ask the patient to switch positions every 30 min to 2 hours ,while looking for improvement in oxygenation, as follows:
  - Lying on right side
  - Sitting up (30-60 degrees) by adjusting head of the bed
  - Lying on left side
  - Lying prone again

12.Ventilatory management:

Indications for intubation:

- Moderate to severe ARDS (PaO2/FiO2 <200)
- Increased work of breathing on non-invasive respiratory support or not tolerating NIV
- Hemodynamic Instability

Initial ventilator setting

Initial ventilator settings

Calculate predicted body weight (PBW)

Male =	50 – 2.3 [height (inches) - 60] OR
	50 – 0.91 [height (cm) - 152.4]
Female =	45.5 + 2.3 [height (inches) - 60] OR
	45.5 + 0.91 [height (cm) - 152.4]

Set mode to volume assist-control

Set initial tidal volume to 6 mL/kg PBW

Set initial ventilator rate ≤35 breaths/min to match baseline minute ventilation

Subsequent tidal volume adjustment

Plateau pressure goal: Pplat ≤30 cm H_2O

Check inspiratory plateau pressure with 0.5 second inspiratory pause at least every four hours and after each change in PEEP or tidal volume.

If Pplat >30 cm H_2O, decrease tidal volume in 1 mL/kg PBW steps to 5 or if necessary to 4 mL/kg PBW.

If Pplat <25 cm H_2O and tidal volume <6 mL/kg, increase tidal volume by 1 mL/kg PBW until Pplat >25 cm H_2O or tidal volume = 6 mL/kg.

If breath stacking (autoPEEP) or severe dyspnea occurs, tidal volume may be increased to 7 or 8 mL/kg PBW if Pplat remains <30 cm H_2O.

Arterial oxygenation and PEEP

Oxygenation goal: PaO_2 55 to 80 mmHg or SpO_2 88 to 95 percent

Use these FiO_2/PEEP combinations to achieve oxygenation goal:

FiO_2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0
PEEP	5	5 to 8	8 to 10	10	10 to 14	14	14 to 18	18 to 24

PEEP should be applied starting with the minimum value for a given FiO_2.

Figure : Protocol for management of ARDS (ARDS.net)

13.Care of ventilated patient:

- Fresh ventilator circuit to be used for every new patient
- Change circuit only when visibly soiled (not routinely)
- Use two HME filters- one at the patient end close to ETT and another at the ventilator end of expiratory limb of circuit. Do not use heated humidifiers
- HME-F to be changed only when visibly soiled
- Use closed inline suction system(avoid open suctioning)
- Use the same closed suction system to collect ET aspirate sample in a mucus trap chamber for RT-PCR
- Do not disconnect the circuit- push twist all connections
- In case disconnection is unavoidable (like patient transport) use deep sedation/muscle relaxation, put the ventilator on standby mode and clamp the ET tube just before disconnection
- Avoid nebulization (use MDI instead)
- Avoid routine airway suctioning

14.Supportive treatment in critically ill patients:

- Head end elevation (30 to 45 degrees), unless contraindicated
- Oral hygiene with mouthwash
- Glycemic control to maintain blood sugar between 140 to 180 mg/dl
- Ulcer prophylaxis with proton pump inhibitors
- LMWH for thromboprophylaxis (as mentioned above)
- Foley's catheter and Ryle's tube placement
- Pressure ulcer prevention by position change every 2 hourly

15.Septic shock:

- Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure ≥ 65 mmHg AND lactate is ≥ 2 mmol/L in absence of hypovolemia.
- Choice of antibiotics: as per indication (community acquired vs hospital acquired) and local antibiogram
- To resuscitate in septic shock give 30 ml /kg of isotonic saline (NS/RL) in first 3 hours, if there is no respond to fluid therapy start vespressor (NORADRENALINE) with a target MAP of >65mm Hg
- If signs of poor perfusion and cardiac dysfunction persist despite achieving target MAP, consider DOBUTAMINE

16. Renal replacement therapy:

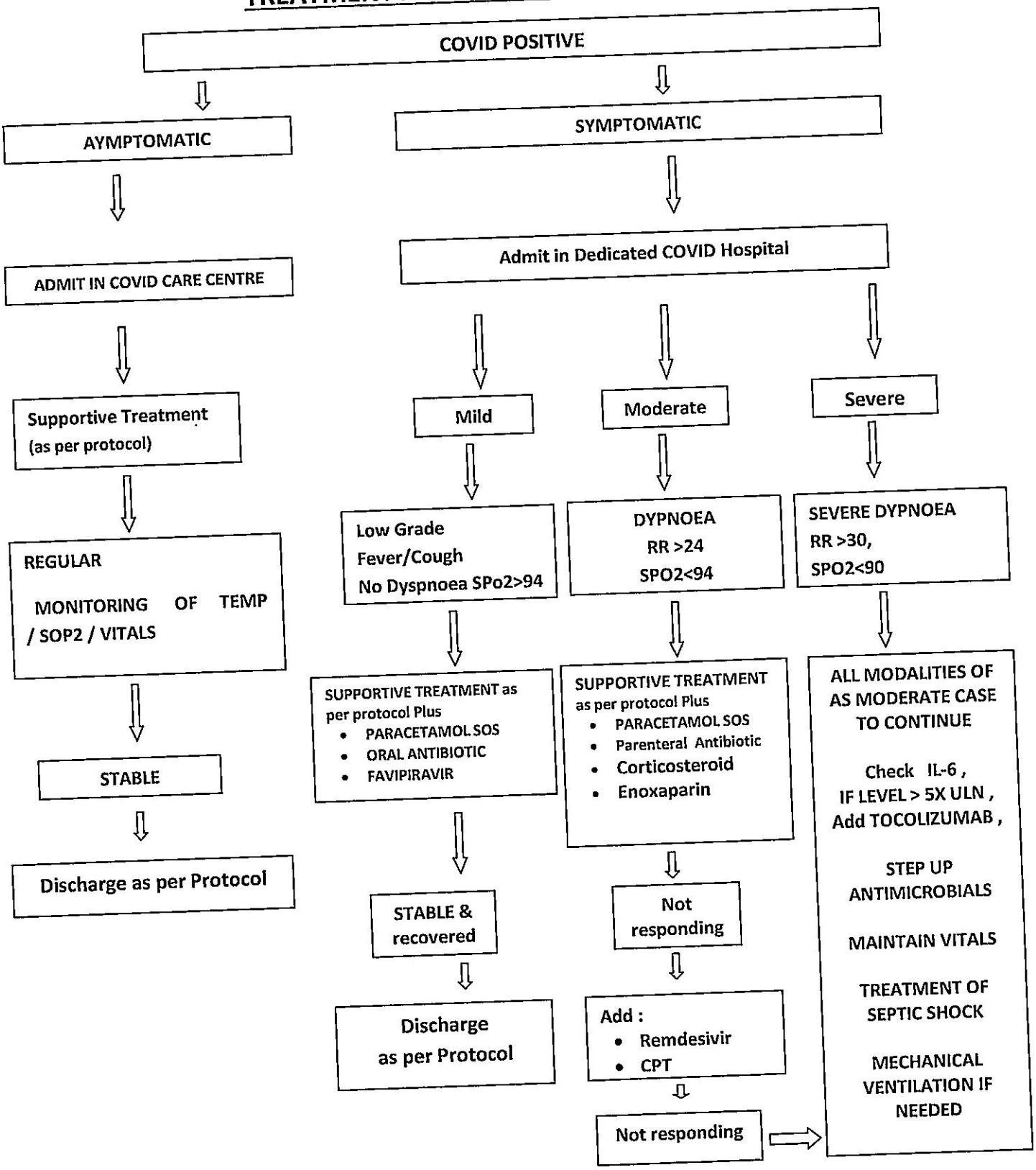
Encephalopathy
Severe metabolic acidosis
Uremic pericarditis
Refractory hyperkalemia
Fluid overload

Renal Replacement Therapy to be done whenever necessary as per institutional protocol.

****

ANNEXURE-II

TREATMENT ALGORITHM FOR COVID-19



ANNEXURE-III

PROTOCOL FOR USE OF CONVALESCENT PLASMA FOR TREATMENT OF PATIENTS WITH COVID 19 INFECTION IN MEDICAL COLLEGE & HOSPITALS

1. **Eligibility of Donor**

   The following criteria should be met for potential donors

   a. More than 18years of age
   b. Only males and nuliparous female donors of weight > 55kg will be included.
   c. Prior diagnosis of COVID -19 documented by a laboratory test (RT-PCR) with symptomatic disease and complete resolution of symptoms at least 28 days prior to donation.
   d. One RT-PCR test for COVID 19 to be done before donation and donors with negative test results only to be considered.

   In addition, donor eligibility criteria for whole blood and plasmapheresis donation will be followed in accordance to the Drugs & Cosmetics Act 1940 and rules 1945 therein (as amended till March 2020).

2. **Informed consent of donors for donating convalescent plasma.**

3. **Screening of eligible donor**

   a. Donor will be screened, followed by brief physical examination.
   b. Donors not fit to donate blood based on the history and physical examination will be deferred.
   c. Donors who have had transfusion of blood products in last 8 weeks will be excluded.
   d. Donors who have had COVID diagnosis more than 4 months will be excluded from donation.
   e. Two EDTA samples (5ml each) and one plain sample (5ml) will be drawn for the following pre-donation tests as required for convalescent plasmapheresis.
      1. Blood group (ABO grouping and Rh phenotyping).
      2. Complete blood count including Hb, Hct,Platelet count, total and differential leucocyte count. Donors with Hb>12.5/dl, platelet count > 1,50,000 per microliter of blood and TLC within normal limits will be accepted.

3. Screening for HIV, HBV, and HCV by serology or NAT. Donor negative by either test will be included.
4. Screening for syphilis and malaria by serology. Negative donors will be included.
5. Total serum protein. Donors with total serum protein>6gm/dl will be accepted (as per Drugs and Cosmetics (Second Amendment)Rules,2020.
6. Neutralizing titre of donor plasma should be above the specific threshold (if the latter is not available, plasma IgG titer (against S-protein RBD) above 1:640 should be used)
7. Molecular test (RT-PCR) for COVID19 will be done. Donors found to be positive will be deferred.
8. Recipient should be closely monitored for several hours post transfusion for any transfusion related adverse events.
9. Use should be avoided in patients with IgA deficiency or immunoglobulin allergy.
10. Consent of the recipient or guardian should be obtained in the format at Annexure-A
11. Roles and Responsibilities of Institutional Medical Board is at Annexure-B.

Annexure-A

INFORMED CONSENT FOR USE OF CONVALESCENT PLASMA THERAPY (CPT) FOR COVID-19 PATIENTS

The institutional medical board has informed me that I...../my relative.....have/has been diagnosed with COVID-19 infection. Further:

- They have clearly explained to me that so far, there is no approved medicine against COVID-19 infection.
- They have informed me/my relative that I /my relative am / is not adequately responding to the standard treatment protocol .
- They have explained to me in detail that there is some scientific evidence regarding the use of Convalescent Plasma Therapy (CPT) for treating COVID-19 infection. This is with the reference to the MoHFW, GOI guideline dated 27-06-2020.
- They have also explained to me that at present a clinical trial is going on in India conducted by ICMR to ascertain the efficacy of CPT in COVID-19 infection in India, in which CPT has been indicated as "OFF Label" therapy in COVID-19 patients.
- They have explained to me that CPT has also been used in the treatment of certain infections like SARS, MERS, Ebola, Influenza etc.
- They have informed me that I/my relative may benefit by the use of CPT.
- They have explained to me that CPT is yet to be approved as a regular therapeutic option for COVID-19. However, at present the same is to be considered as an investigational therapeutic option.
- They have explained to me about the possible side effects of CPT.
- They have also made it clear to me/my relative that the standard treatment for COVID 19 will be continued irrespective of my decision regarding the use of CPT.

Now having the full knowledge as above, I agree to give my consent for the application of CPT in the treatment of my/my relative's COVID19 infection.

Name of declarant:

Relation with patient:

Name of patient:

Signature & Date:

Place:

Acceptance of Institutional Medical Board Members

Annexure-B

ROLES AND RESPONSIBILITIES OF INSTITUTIONAL MEDICAL BOARD

1. Monitoring of the baseline clinical and biochemical parameters should be done and recorded in a case report form. Biochemical parameters ideally should include CRP, D-dimer, LDH, S.ferritin, T-protein prior to convalescent plasma administration and should be repeated every 48hours for a week.
2. All the recorded details should be sent to State Medical Board by the Institutional Medical Board.
3. All the adverse events observed should be reported to State Medical board.

Composition of Boards

Institutional Medical Board:

- Representative of Hospital authority.
- Pulmonologist.
- Physician.
- Blood bank in charge.

State Medical Board:

- Representative of Health and Family welfare department.
- Representative of State Blood Transfusion Council.
- Representative of ASACS
- Representative of State Drugs Controller.
- Registrar, Assam Council of Medical Registration.