COVID-19 IMMUNOGLOBULIN DOMAIN ADMINISTRATION GUIDE

SECTION 1: REMAP-CAP COVID-19 IMMUNOGLOBULIN DOMAIN INTERVENTIONS

This domain aims to determine the effectiveness of different immunoglobulin strategies for immunosuppressed patients with confirmed COVID-19. In this domain, patients are randomised to receive:

- No immunoglobulin against COVID-19
- High titre convalescent plasma

The allocated intervention should be commenced immediately following allocation reveal at time of confirmation of infection by microbiological testing.

SECTION 2: NO COVID-19 IMMUNOGLOBULIN INTERVENTION

Intervention
Patients allocated to the *no immunoglobulin intervention* must not receive any preparation of polyclonal immunoglobulin intended to neutralize SARS-CoV-2 during this hospitalisation. Administration of such a preparation is considered a protocol deviation. Administration of a monoclonal antibody preparation is permitted prior to randomisation to this domain.

Discontinuation of intervention
Withholding of immunoglobulin therapy for the treatment of COVID-19 is to continue until hospital discharge.

SECTION 3: CONVALESCENT PLASMA INTERVENTION

Intervention
Patients allocated to the *convalescent plasma intervention* should receive two adult units of ABO compatible convalescent plasma (total volume 550ml ± 150ml) within 48 hours of randomisation. Convalescent plasma must be high titre plasma derived from whole blood or apheresis from vaccinated donors who have also had a natural infection.

Dosing
The patient should be prescribed two units of ABO compatible high titre convalescent plasma (total volume 550ml ± 150ml) within 48 hours of randomisation. The second unit should be omitted if the patients experiences a serious adverse reaction following administration of the first unit. Volume of convalescent plasma administered will be recorded and where available the level of antibodies within each unit will be tested.

After the first unit is transfused, provided the patient has not had any serious adverse reactions, the second unit of convalescent plasma should be administered. Each unit should be given as a separate transfusion and both units should be given within 48 hours of randomisation. Ensure timely communications to the transfusion laboratory staff to facilitate this.

It will be considered a protocol deviation if no convalescent plasma has been transfused within 48 hours after reveal of allocation.

Administration of convalescent plasma continued on next page

SECTION 3: CONVALESCENT PLASMA INTERVENTION (CONTINUED)

Administration

Process for issuing each separate unit of convalescent plasma is as follows:

- Convalescent plasma should be prepared and administered as per local standard procedures for fresh frozen plasma
- All administration bedside transfusion safety checks must be undertaken.
- The donation number, volume transfused, and start and finish date and time of transfusion should be documented in the patient's clinical record.
- Any suspected serious adverse reaction to transfusion must be reported to the transfusion laboratory as well as being reported on trial documentation.

Duration of intervention

Timing of intervention is to commence as soon as possible after allocation status is revealed.

If the patient has no serious adverse reactions to the first unit transfusion the second unit of convalescent plasma will be given. Both transfusions should be given within 48 hours from reveal of allocation.

SECTION 4: CONCOMITANT CARE

Additional immunoglobulin therapy intended to be active against SARS-CoV-2 infection (such as monoclonal antibodies, hyperimmune globulin or convalescent plasma) should not be administered after randomisation.

There are no other restrictions on concomitant care. All treatment that is not specified by assignment within the platform will be determined by the treating clinician.