PATIENT CONSENT FORM
EXPERIMENTAL USE OF TOCILIZUMAB
IN HOSPITALISED ADULTS WITH COVID-19

The use of medicines to treat COVID-19 infection is largely experimental with information continuing to be gathered. Tocilizumab (Actemra®) is registered for use in Australia for the treatment of arthritis, giant cell arteritis and cytokine release syndrome, but not for the treatment of COVID-19 infection.

PATIENT CONSENT

By signing this form, I _____ understand that:
(write name of patient / authorised representative)

- tocilizumab (Actemra®) is not registered for use in Australia for the treatment of COVID-19;
- there are no guarantees of the effectiveness of tocilizumab when it is used experimentally to treat COVID-19 and I may not experience any benefit;
- there are no guarantees of the safety of tocilizumab when it is used experimentally to treat COVID-19 and even with careful precautions in place, unforeseen complications may occur;
- there is potential for drug interactions (known and unknown) with the use of tocilizumab; and,
- there is a possibility of experiencing side effects with the use of tocilizumab (known and unknown).

I confirm that I have had the opportunity to ask questions and I am satisfied with the explanation and the answers to my questions.

I understand that I can change my mind and withdraw my consent to being treated with tocilizumab at any time.

With this knowledge, I **consent** to the experimental use of tocilizumab in the treatment of me/the person I am responsible for.

Patient's name: _____

Signature of patient (or authorised representative*): _____ **Date:** ____/____/____

Name & signature of witness: _____ **Date:** ____/____/____

Witness is not to be a member of the treating team. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

*If the authorised representative has signed, please provide details below:

Name: _____ **Date of Birth:** ____/____/____

Address: _____ **Contact Number:** _____

Relationship to patient: _____ **Reason for representation:** _____

DOCTOR'S DECLARATION

☐ I have provided to the patient/their authorised representative an explanation of the experimental use of tocilizumab, its potential benefits and harms and the relevant **Patient Information Leaflet**.
I believe the information has been understood.

Doctors name: _____ **Signature:** _____ **Date:** ____/____/____

If the patient cannot converse adequately in English, please use an accredited Health Care interpreter. Do not rely on relatives or other parties for interpreting.

Language: _____ **Name of interpreter:** _____

Signature: _____ **Date:** ____/____/____

Completed signed form should be kept in the patient's Health Record.

NSW Therapeutic Advisory Group does not endorse the use of tocilizumab for COVID-19 outside a clinical trial setting.
This consent form is provided to support clinicians if tocilizumab is used experimentally outside a trial setting.
See http://www.nswtag.org.au/resources-for-experimental-medicines-for-the-treatment-of-covid-19/ for further details.

NSW TAG NSW Therapeutic Advisory Group Inc.