General instructions for completing clozapine protocol forms
- In order to comply with medical record standards, all components of the form must be completed in full. Incomplete entries are not valid.
- Please ensure that when completing the weekly/4 weekly review all boxes have information entered.
- All entries must be completed with a date, signature, name, designation and time.
- The review must be completed by one person at the time of seeing the participant for the face to face assessment for signs and symptoms of infection.
- The full completion of this form is the minimum requirement for all participants prescribed clozapine under the TGA endorsed clozapine management protocols. Further monitoring may be required by individual health networks.
- Doctors prescribing clozapine must be registered with the monitoring provider (refer to your local clozapine coordinator for more information).

Clozapine Review Guidelines

<table>
<thead>
<tr>
<th>Clinical Information</th>
<th>Side effects</th>
<th>Extra monitoring required etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual review</td>
<td>Clozapine level</td>
<td>Fasting blood glucose level</td>
</tr>
<tr>
<td></td>
<td>Fasting lipids</td>
<td>Liver function test (LFT)</td>
</tr>
<tr>
<td></td>
<td>Electrolytes</td>
<td>Complete blood examination (CBE)</td>
</tr>
<tr>
<td></td>
<td>C-Reactive Protein (CRP)</td>
<td>Electrocardiograph (ECG)</td>
</tr>
<tr>
<td></td>
<td>Troponin</td>
<td>ECHO</td>
</tr>
<tr>
<td>6 monthly review</td>
<td>Clozapine level</td>
<td>Fasting blood glucose level</td>
</tr>
<tr>
<td></td>
<td>Fasting lipids</td>
<td>Liver function test (LFT)</td>
</tr>
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<td></td>
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<td>Complete blood examination (CBE)</td>
</tr>
</tbody>
</table>

Shared Care
- Contact monitoring doctor 3 monthly
- Assess clozapine management plan
- Collect physical and metabolic health data
- Remind/advice doctor regarding 6 month and annual review pathology and cardiac monitoring requirements
- 6 Monthly psychiatrist review

Cardiac Monitoring Guidelines
- First 28 days
  - At all times: Educate participants and carers to report flu-like symptoms, GI upsets, dizziness or chest pain.
  - Once a day: Measure body temperature at the same time each day.
  - Weekly (days 7, 14, 21 and 28): Troponin T or I, CRP, Pulse, Blood Pressure, Respiratory rate.
  - If at any time: Temperature > 38°C or flu-like symptoms: C-Reactive Protein (CRP), Troponin, and CBE.
- Tropinon > 2 ULN and CRP elevated: Urgent transfer to Emergency department, Urgent cardiology consultation – query myocarditis, Urgent echocardiography.
- Tropinon > 2 ULN and normal CRP: Urgent transfer to Emergency department, Urgent cardiology consultation – query ACS (acute coronary syndrome).
- Tropinon 1 to ≤ 2 ULN and elevated CRP: Urgent cardiology consultation. Daily assess troponin, CRP and symptoms until features normalised. Clozapine treatment can continue if not contraindicated by ongoing assessment.

CLOZAPINE PROTOCOL INFORMATION

This form is for 4 weekly monitoring of clozapine, and is designed to meet the checks and observational needs of the participant.

Clozapine is a medication regulated by the TGA, subsidised under the Highly Specialised Drugs Program. It is a third line treatment for chronic schizophrenia refractory to treatment with other medications. Participants may only be prescribed clozapine when mandatory blood testing and other monitoring can be achieved in the community.

Side effects
- Weight gain
- Metabolic syndrome
- Diabetes
- Hyper-salivation (more often at night)
- Nausea
- Sedation
- Seizures
- Hypertension/hypotension
- Myocarditis
- Cardiomyopathy
- Pulmonary embolism
- Acute renal failure

Life threatening events
- Agranulocytosis/neutropenia
- Severe infections

If any of the above adverse events are noted, please refer to the Adverse Event Protocols.

Recommencing clozapine after a period of interruption:
Clozapine must be re-tritrated from 12.5mg if the participant has missed the medication for more than 48 hours to reduce the risk of serious side effects. There are also additional monitoring requirements depending on the period of interruption. See table below:

<table>
<thead>
<tr>
<th>Period of Interruption (time since last dose was taken)</th>
<th>Dosage / Monitoring Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 48 hours</td>
<td>No change to dosage or monitoring</td>
</tr>
<tr>
<td>&gt; 48 hours &amp; ≤ 72 hours</td>
<td>Start on 12.5mg and titrate up</td>
</tr>
<tr>
<td>&gt; 72 hours &amp; ≤ 28 days</td>
<td>No additional monitoring requirements</td>
</tr>
<tr>
<td>For 4 Weekly participants: Weekly monitoring for 6 weeks. If no abnormality, resume 4 weekly monitoring</td>
<td></td>
</tr>
<tr>
<td>For Weekly participants: Weekly monitoring for 6 weeks or as long as needed to reach 18 weeks (whichever is the greatest).</td>
<td></td>
</tr>
<tr>
<td>&gt; 28 days</td>
<td>New participant registration form</td>
</tr>
<tr>
<td></td>
<td>New pre-treatment result and monitoring same as new participant (18 weeks); no 6 hour vital signs monitoring required</td>
</tr>
<tr>
<td></td>
<td>Start on 12.5mg and titrate up.</td>
</tr>
</tbody>
</table>

WCC and NC
- WCC >3.5 x 10^9/L and NC >2.0 x 10^9/L: GREEN Clozapine therapy can continue or be titrated upwards as required
- WCC 3.0-3.5 x 10^9/L and/or NC 1.5-2.0 x 10^9/L: AMBER Requires increasing frequency of monitoring, to twice weekly
- WCC <3.0 x 10^9/L and/or NC <1.5 x 10^9/L: RED STOP clozapine immediately and repeat blood test within 24 hours. Contact Consultant Psychiatrist and arrange urgent medical review
The image contains a clinical protocol form with various patient information fields and medical review sections. The protocol appears to be for clozapine therapy, with specific instructions and review dates. It includes sections for identifying the patient, their medical history, medication details, and clinical reviews. The form contains checkboxes and fields for various medical parameters such as weight, blood pressure, temperature, and other clinical measurements.

The table section of the form is divided into columns for different dates and parameters, indicating a structured review process. Each column corresponds to a specific month, and the form requests entries for different clinical measurements such as weight, blood pressure, temperature, and other vital signs.

The form also includes sections for pathology review due dates, medication reminders, and shared care notes. There is a section for the signature of the person completing the form.