Government of **Western Australia**
Department of **Health**

THIS CONSENT FORM MUST BE RETAINED IN THE PATIENT'S MEDICAL RECORD

WA PATIENT CONSENT FORM - Use of *SOTROVIMAB* in patients with COVID-19

SOTROVIMAB (Xevudy®) infusion for the treatment of COVID-19 (referred to as **"Treatment"** in this form), is a *provisionally* registered medicine by the Therapeutic Goods Administration for use in Australia in line with National COVID-19 Clinical Evidence Taskforce recommendations.

By signing this consent form, I understand that: _____

(write full name of the person signing this form)

- This treatment is provisionally registered for use in Australia for the treatment of mild to moderate COVID-19 and more information about its effectiveness and safety is required before it can be fully registered.
- There are no guarantees of the effectiveness of this treatment when it is used to treat COVID-19 and I may not experience any benefit.
- There are no guarantees of the safety of this treatment when it is used to treat COVID-19 and despite appropriate precautions in place, unforeseen complications may occur.
- There is potential for medicine interactions (known and unknown) with the use of this treatment.
- This treatment may reduce my response to vaccines given within 90 days (before or after) treatment administration.
- There is a possibility of experiencing side effects (known and unknown) with the use of this treatment.
- I may be contacted by the Department of Health or my doctor about my outcomes related to the Treatment.

PATIENT CONSENT

- I have been informed of and understand the risks that are specific to me, the benefits, the alternatives (including if I choose not to have the Treatment), and the likely outcomes.
- I have been given the opportunity to ask questions about this Treatment and my specific queries and concerns have been answered.
- I understand that my consent to the Treatment is voluntary. I have the right to change my mind and can withdraw my consent to Treatment at any time before the Treatment is performed, including after I have signed this form. I understand that I must inform my doctor/health practitioner if this occurs.
- I consent to undergo the Treatment as documented on this form.

Patient's full name (printed):		**UMRN:**	
Patient's signature:		**Date:**	
	(including mature minors, or signature of parent / legal guardian)		
If the patient has been deemed to not have capacity to consent:	**Reason patient is incapable of consenting to treatment (tick one):** ☐ Patient is unconscious ☐ Patient has diminished consciousness (i.e. related to medication or other drug use or extreme pain) ☐ Patient is cognitively impaired		

DETAILS OF SUBSTITUTE DECISION MAKER (if applicable)

Full name (printed):		**Contact number:**			
Address:					
Suburb:		**State:**		**Postcode:**	
Relationship to patient:		**Reason for representation:**			

DOCTOR / HEALTH PRACTITIONER DECLARATION

Risks and benefits of treatment have been discussed with the patient / substitute decision maker and relevant consent discussions are documented within this form and/or within the patient's medical record.

☐Written consent ☐Verbal Consent (see over page) ☐ Patient provided with a sotrovimab Patient Information Sheet

Doctor / Health Practitioner's full name (printed):		**Date:**	
Position / Title (printed):			
Doctor / Health Practitioner's signature:			

Please see reverse for verbal consent and interpreter declaration

INTERPRETER'S DECLARATION (if applicable)			
Specific language services required:			
I declare that I have interpreted the dialogue between the patient and the doctor / health practitioner about the Treatment to the best of my ability and have advised the doctor / health practitioner of any concerns about my interpretation of this dialogue.			
Interpreter's full name (printed):		**Date:**	
Agency name:		**NAATI number:**	
Interpreter's signature:			
Interpretation took place (tick one):	☐ In person ☐ Via phone / videoconference		

SIGNATURE OF SECOND / WITNESSING DOCTOR / HEALTH PRACTITIONER FOR VERBAL CONSENT (if applicable)			
Risks and benefits of treatment have been discussed with the patient / substitute decision maker and relevant consent discussions are documented within this form and/or within the patient's medical record.			
Doctor / Health Practitioner's full name (printed):		**Date:**	
Position / Title (printed):			
Doctor / Health Practitioner's signature:			

PROVISION OF INFORMATION IF OBTAINING VERBAL CONSENT

1. **Introduce yourself to the patient/person responsible and confirm relevant patient identifying information.**
2. *I'm here to provide information about a new medicine, sotrovimab, which may be used to treat some cases of mild or moderate COVID-19 and get your consent for its use by you/the person you are responsible for. It is important that you understand the possible benefits and harms of this treatment.*
3. *You have been provided with the Patient Information Leaflet which provides information about sotrovimab to treat COVID-19 in you/the person you are responsible for.*

Whenever possible, provide the relevant Patient Information Leaflets to the patient/person responsible beforehand. There may be a need to provide further explanations regarding use in some populations.

4. *Sotrovimab (Xevudy®)*
   - ***a.*** *Sotrovimab is a new medicine that acts against the COVID-19 virus. It is provisionally approved for use in Australia to treat mild to moderate COVID-19 in people who do not need oxygen but are at risk of COVID-19 becoming more severe. More information about its effectiveness & safety is needed before it is fully approved in Australia.*
   - ***b.*** *Sotrovimab works by blocking the virus entering human cells and multiplying in the body. If it is used within 5 days of onset of COVID-19 symptoms, sotrovimab probably reduces the risk of being admitted to hospital or dying.*
   - ***c.*** *So far, sotrovimab has shown a good safety profile. Some possible side effects that might be experienced are listed in the information leaflet. These include reactions while sotrovimab is being given such as fever, chills, itchiness, rash, headache or dizziness. Very rarely, a person receiving sotrovimab has had a severe allergic reaction and needed treatment. Immediately tell the doctor or nurse looking after you if you think you are having a side effect.*
   - ***d.*** *Because it is a new medicine, there is a possibility of experiencing other unknown side effects when it is used in people with COVID-19.*
   - ***e.*** *Sotrovimab is given by infusion into a vein over 30 minutes. We will closely observe you for one hour after the infusion has been given, to check for any immediate side effects.*
5. *It is important for you to know and understand that:*
   - ***a.*** *there are no guarantees of the effectiveness of sotrovimab when used to treat COVID-19 and you/the person you are responsible for may not experience any benefit;*
   - ***b.*** *there are no guarantees of the safety of sotrovimab and it may cause side effects when used to treat COVID-19 and, even with careful precautions in place, unforeseen complications may occur; and,*
   - ***c.*** *this is a new drug with no known drug interactions. However, sotrovimab can reduce effectiveness of vaccines given recently before or after treatment. (Please ask your doctor about your future vaccinations when you have recovered from COVID-19).*
6. *Your consent to treatment with sotrovimab is voluntary. If you do not want to have treatment with sotrovimab, you do not have to. You can always change your mind about treatment and withdraw consent at any time; just let one of the healthcare team members know.*
7. *Do you have any questions about the information provided, or any other questions about sotrovimab being used in the treatmer of COVID-19?*
   - ***a.*** **If yes, answer any questions the patient may have. If no, continue to collect consent.**
8. *Do you agree to be contacted by the Department of Health or your doctor in the future about your outcomes related to the Treatment or outcomes of treatment for the person you are responsible for?*
   - **a. Record the answer given by the patient and continue to collect consent for treatment.**
9. *Now that I have provided you with this information, can you* **[state name of patient/person responsible]** *please confirm that:*
   - ***a.*** *you understand the proposed use of sotrovimab including the possible benefits and harms?*
   - ***b.*** *you have had an opportunity to ask questions and you are satisfied with the answers you have received?*
   - ***c.*** *you freely agree to treatment with sotrovimab?*
     - **If no, thank the participant for their time and end the consent process.**
     - **If yes, ensure you record the date the verbal consent was collected.**

Ensure that all parts of the form are completed. The consent form must be retained in the patient's medical records.