



Australian Government

Department of Health and Aged Care  
Office of the Gene Technology Regulator

28 October 2024

## Invitation to comment on a clinical trial for the treatment of bacterial infections using bacteriophages (DIR-206)

The Gene Technology Regulator is assessing an application from Western Sydney Local Health District (WSLHD) to conduct a clinical trial, under limited and controlled conditions, of genetically modified bacteriophages for the treatment of mycobacterial infections. The trial is proposed to take place at clinical trial sites and hospitals in Australia. At least 3 trial participants would be treated over a 5-year period.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions relating to the protection of human health and safety and the environment prior to making a decision on whether to issue the licence. The consultation RARMP and related information can be obtained via our website (search for [DIR-206](#)), or from the contacts below. Submissions should reference DIR-206 and be received by **9 December 2024**.

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