



Australian Government

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

17 February 2025

Notification of decision on application DIR 206 from Western Sydney Local Health District for a clinical trial for the treatment of mycobacterial infections using bacteriophages

The Regulator has issued licence DIR 206 to Western Sydney Local Health District (WSLHD), authorising a clinical trial of genetically modified bacteriophages.

The clinical trial is authorised to take place throughout Australia.

The Risk Assessment and Risk Management Plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

Submissions are summarised in Appendix A and Appendix B of the RARMP, together with information about how the issues raised relating to risks to human health and safety or the environment were considered in finalising the RARMP.

The finalised RARMP concludes that this clinical trial poses negligible risks to the health and safety of people and the environment, thus it does not require specific risk treatment measures. However, licence conditions have been imposed to, limit the location of the clinical trial to hospitals, clinical trial sites or under the Hospital in the Home program, limit the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread in the environment, as these were important considerations for the RARMP.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the [DIR 206](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

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