



Australian Government

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

NOTIFICATION OF APPLICATION

Receipt of licence application from the Western Sydney Local Health District (WSLHD) for *Clinical trial for the treatment of mycobacterial infections using bacteriophages*

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR-206) from the Western Sydney Local Health District (WSLHD). This application is to administer bacteriophages genetically modified to kill mycobacteria responsible for recurrent bacterial infections in patients. A summary of the application is posted on our [website](#) (search for [DIR-206](#)).

The trial is proposed to take place at clinical sites and potentially in the homes of patients over a period of 5 years. Patients within Australia who are eligible under the Special Access Scheme categories A or B would receive bacteriophage therapies administered by various methods including via nebuliser, by intravenous injection, instillation, or topical application for the treatment of mycobacterial infections.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. The RARMP will be prepared taking into account advice received from a broad range of experts, agencies and authorities, and relevant local councils, as specified in the *Gene Technology Act 2000*. This is expected to be released for public comment and advice from experts, agencies and authorities in **mid-August 2024**. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the application or the summary, please contact the OGTR and quote the reference number DIR-206.

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