# 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](https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release) (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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