

## NOTIFICATION OF APPLICATION

### ***Receipt of licence application from Doherty Clinical Trials Ltd for Clinical trials of controlled infection with seasonal Influenza viruses***

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 210) from Doherty Clinical Trials Ltd (DCT) to conduct clinical trials involving recombinant influenza viruses produced through reverse genetics. A summary of the application is posted on our [website](#) under News.

Clinical trials will be conducted at the DCT Clinical trial facility in Melbourne over a period of five years. These clinical trials will study the safety and infectivity of genetically modified (GM) seasonal human influenza viruses in healthy volunteers. These GM influenza viruses will also be used to assess the efficacy of various vaccines and the therapeutic effect of commercial drugs for the treatment of influenza.

The OGTR is preparing a Risk Assessment and Risk Management (RARMP) 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 December 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 full application or the summary, please contact the OGTR and quote the reference number DIR 210.

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