Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Invitation to comment on Clinical trials of controlled infection with seasonal influenza viruses (DIR 210)

The Gene Technology Regulator is assessing an application from Doherty Clinical Trials Ltd to conduct clinical trials involving recombinant influenza viruses. Clinical trials will be conducted at the DCT Clinical trial facility in Melbourne. 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 therapeutic efficacy of various potential vaccines and drugs for the treatment of influenza. Up to 150 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 210), or from the contacts below. Submissions should reference DIR 210 and be received by **7 February 2025**.

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