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

2 April 2025

Notification of decision on application DIR 210 from Doherty Clinical Trials Ltd for the Clinical trials of controlled infection with seasonal influenza viruses

The Regulator has issued licence DIR 210 to Doherty Clinical Trials Ltd, authorising the clinical trials of controlled infection with seasonal influenza viruses.

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 these clinical trials pose negligible to moderate risks to the health and safety of people and the environment, based on the pathogenicity of circulating influenza and requires specific risk treatment measures. Strict licensing conditions have been imposed on the number of trial participants, the facility used, work practices, and specify various controls to minimise the potential for the GMO to spread in the environment.

The finalised RARMP, a summary of the RARMP, the licence, and Questions and Answers about this decision can be obtained online from the DIR 210 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below

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