



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

10 June 2020

**Notification of decision on application DIR 171 from Clinical Network Services (CNS) Pty Ltd for a clinical trial of genetically modified influenza vaccine**

The Regulator has issued licence DIR 171 to Clinical Network Services (CNS) Pty Ltd, authorising a clinical trial of a live genetically modified (GM) vaccine for protection of people against *Influenza virus* infection.

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 preparing and finalising the RARMP.

The finalised RARMP concludes that this clinical trial poses negligible risks to the health and safety of people and the environment, thus it does not require specific risk treatment measures. However, licence conditions have been imposed to limit the size, location and duration of the clinical trial and to restrict spread and persistence of the GMOs and their genetic material in the environment, as these were important considerations for the RARMP.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the [DIR 171](#) page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

**Office of the Gene Technology Regulator**

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