Australian Government

Department of Health and Aged Care

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of a genetically modified human adenovirus for treatment of melanoma (DIR 213)

The Gene Technology Regulator is assessing an application from Novotech (Australia) Pty Ltd to conduct a clinical trial, under limited and controlled conditions, of a genetically modified human adenovirus for treatment of melanoma. The trial is proposed to take place at clinical trial sites and hospitals in Australia. Up to 30 trial participants would be treated over a 3 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 the consultation hub (search for DIR 213), or from the contacts below. Submissions should reference DIR 213 and be submitted via the hub or email by **6 May 2025**.

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