



Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

Invitation to comment on a clinical trial of a genetically modified *Escherichia coli* for the treatment of ulcerative colitis (DIR 221)

The Gene Technology Regulator is assessing an application from Melius MicroBiomics Pty Ltd to conduct a clinical trial, under limited and controlled conditions, of a genetically modified *Escherichia coli* for the treatment of ulcerative colitis. The trial is proposed to take place at a hospital or clinical trial sites in Brisbane. Up to 36 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 the [consultation hub](#), or from the contacts below. Submissions should reference DIR 221 and be received by **14 January 2026**.

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