# Questions & Answers on licence DIR 221 – Clinical trial of a genetically modified *Escherichia coli* for the treatment of ulcerative colitis

**What does this licence allow?**

Melius MicroBiomics Pty Ltd has been issued a licence to conduct a clinical trial, under limited and controlled conditions, of a genetically modified (GM) *E. coli* for the treatment of ulcerative colitis.

Probiotics containing the unmodified parental *E. coli* Nissle strain 1917 (EcN) have been used for the treatment of ulcerative colitis. It is predicted that the GM *E. coli* would be able to persist longer in the gut of participants with ulcerative colitis and improve its therapeutic effect. The GM *E. coli* would be manufactured overseas and imported into Australia. It would be administered to up to 36 participants at a hospital or clinical trial sites in Brisbane.

**How has the GM *E. coli* been modified?**

The GM *E. coli* is based on the EcN probiotic strain, which has been used for over 100 years. The GM *E. coli* has been modified by the insertion of a gene that allows it to persist longer in inflammatory conditions, common in the gut of people with ulcerative colitis. The GM *E. coli* has also been modified to reduce its ability to persist outside the body in the broader environment.

**What is the purpose of the trial?**

The trial is to assess the safety and efficacy of the GM *E. coli* for the treatment of ulcerative colitis.

**What other regulatory processes apply to this trial?**

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration (TGA), which address the safety of trial participants. Before commencing, the trials would require ethics approval and must be conducted in accordance with the Guidelines for Good Clinical Practice. Import of the GM *E. coli* will also require approval from the Department of Agriculture, Forestry and Fisheries.

**What controls are imposed for this release?**

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the clinical trial poses negligible to low risks to people and the environment. Strict licence conditions have been imposed to manage these risks. These conditions limit the number of trial participants, the location of the clinical trial, the duration of the trial, and specify a range of controls to minimise the potential for the GMO to spread in the environment. For example, there are conditions relating to secure transport and storage of the GMO, hygiene measures for trial participants, and appropriate waste disposal. Full details of these risk treatment measures are in the licence.

**Want more information?**

A number of documents relating to this decision are available on the DIR 221 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

**The Office of the Gene Technology Regulator**

**Tel: 1800 181 030 E-mail: ogtr@health.gov.au**

**OGTR Website**