# Questions & Answers on licence application DIR 183 – Clinical trial with genetically modified *E.coli* to reduce antibiotic resistance

**What does this licence allow?**

The Westmead Institute for Medical Research is conducting a clinical trial with genetically modified (GM) *E.coli* to reduce antibiotic resistance. This trial aims to treat 100 participants over 5 years. To be eligible, participants need to have bacteria carrying a specific type of antibiotic resistance. They will be treated under carefully controlled conditions at Westmead Hospital in Sydney.

**How has the GM treatment been designed?**

Genes that mediate antibiotic resistance are often found in DNA packages called plasmids. The treatment uses a modified form of a common probiotic bacteria, *E.coli* which contains a GM plasmid that can replace the antibiotic-resistance plasmid present in harmful gut bacteria. The GM probiotic bacteria is ingested by the trial participant with the aim of colonising their gut. The GM probiotic bacteria will then deliver its GM plasmid to harmful gut bacteria replacing the problematic antibiotic resistant genes. This should restore susceptibility of potentially deadly bacteria to normal antibiotic treatment and help patients overcome potential infections.

**Has the GM treatment been previously tested or used?**

Preclinical experiments were conducted to show the proof-of-principle and safety of the treatment. This is the first human trial of this treatment.

**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*.

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

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that this clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, a number of licence conditions have been drafted to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM treatment. For example, there are conditions relating to preparation and administration of the GM treatment, secure transport and storage of the GM treatment and appropriate waste disposal. Full details of the licence conditions are available in the final RARMP.

**Want more information?**

A number of documents relating to this decision are available on the DIR 183 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**

**OGTR Website**

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