



Home Office

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What will happen to animals at the end of this project?

- Killed

## Replacement

State what non-animal alternatives are available in this field, which alternatives you have considered and why they cannot be used for this purpose.

Why do you need to use animals to achieve the aim of your project?

With current scientific product development a biologic with prophylactic or therapeutic properties (that is to be assessed in humans) it is required that efficacy is first demonstrated in one and preferably two animal models should they exist. In the case of *C. difficile* infection both mice and hamsters provide determination of whether a treatment option can prevent infection. Use of both animal systems is recognised by the worldwide scientific community as is evident from the plethora of international publications relating to this disease. Accordingly, regulators who facilitate evaluation of a biologic in humans will demand evidence that a product demonstrates efficacy using established animal models of infection.

Which non-animal alternatives did you consider for use in this project?

Currently, there are no non-animal alternatives available. It is worth emphasising that the decision to enter animal testing is

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Previous studies will have used power calculations to determine group sizes and the validity of these calculations demonstrated from previous studies. As a rule, numbers of animals used per group should be sufficient to enable statistical significance between groups. Since the studies contained here have the same primary objectives we can use the same group sizes. If the primary objective will be different a new power calculation will be performed to determine animal numbers.

We plan for between 30 and 40 animals per group.

From the primary objective to determine the same groups.

From the primary objective to determine the same groups.



