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## **Bioethics Position Statement: Choice of Control in Clinical Trials I: Use of Placebo Control**

A placebo control is an inactive agent used as a baseline for comparison against a test treatment in a clinical trial. Placebo control is often considered scientifically necessary to obtain valid trial results. However, there is concern that placebo control is ethically problematic because individuals who receive placebo are not receiving an established effective treatment.

Lilly believes that the use of placebo control in the development of new medicines can be scientifically valuable and ethically justifiable. When there are no established effective treatments for a disease or condition, the use of placebo control is generally appropriate. Even in some diseases or conditions for which an established effective treatment is available, the judicious use of placebo control is ethically justified if the following conditions are satisfied:

- There are scientifically sound methodological reasons to use a placebo control.
- Withholding an established effective treatment will not result in irreversible disease progression, prolonged non-trivial disability, or undue suffering.
- Research participants participate in a robust informed consent process and provide voluntary informed consent.

Only after a careful analysis of scientific and ethical considerations, risks to research participants, and local regulatory requirements will Lilly decide to conduct a placebo-controlled trial.

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