



GUIDELINE FOR THE USE OF PLACEBO IN CLINICAL RESEARCH

The guidance below is provided to be consistent with literature in research ethics, guidance from federal regulatory agencies, current RSRB operations, and accepted procedures and practices in regard to the use of placebo in clinical trials.

The RSRB does not permit the use of placebo in the following scenarios:

1. Where use of placebo in the research might cause potential permanent harm from delay of or withholding a known active treatment.
2. Research concerning immediately life-threatening diseases.
3. Placebo is used in lieu of a known active treatment.

The RSRB will consider the use of placebo under the scenarios described below. The protocol should adequately describe stopping rules/withdrawal criteria, rescue medication, if available, and the consent should clearly indicate the risk of receiving 'no treatment' (i.e., placebo).

1. The proposed research does not involve the use of placebo in lieu of a known and available active treatment, the research is adequately justified scientifically through the Investigator's department scientific review process (see OHSP policy on Scientific Review for Human Subjects Research), and is adequately justified ethically as determined by the RSRB.
2. An investigational agent (i.e., drug/device/biologic) and its placebo control is in addition to standard of care and does not otherwise alter standard of care, the use of placebo is adequately justified as determined by the RSRB, and the use would not jeopardize clinical care or present more than a temporary inconvenience.
3. The investigational agent used in the research does not have an equivalent approved treatment for the research population.