Placebo Algorithm

An Algorithm for IRB Evaluation of Studies That Involve Placebo

Is placebo being used in place of standard therapy?

YES

Is standard treatment considered to be effective?

YES

Is the toxicity of standard therapy such that patients routinely refuse treatment?

NO

THE USE OF PLACEBO IS ETHICAL.

YES

THE RISK OF PLACEBO IS HIGH. ADDITIONAL PROTECTIONS ARE REQUIRED THAT RECOGNIZE THE FACT THAT INFORMED CONSENT IS OFTEN SUBOPTIMAL. AN IMPORTANT CONSIDERATION IS A STUDY DESIGN THAT MINIMIZES RISK.

CONSIDER ALTERNATE STUDY DESIGNS: Is it possible to predict the placebo response rate in this study with a reasonable degree of accuracy?

NO

YES

THE USE OF PLACEBO IS ETHICAL.

A STUDY WITH CONCOMITANT PLACEBO CONTROL IS NOT ETHICAL. ALTERNATIVE STUDY DESIGNS ARE LIKELY TO PRODUCE MEANINGFUL RESULTS WITH LESS RISK TO SUBJECTS.

EVALUATE THE CREDIBILITY OF ALTRUISM: Could this trial benefit future patients to the point that a reasonable person with an average degree of altruism and risk-averseness would consent to being randomized in this trial?

YES

THE USE OF PLACEBO IS ETHICAL.

NO

A STUDY WITH CONCOMITANT PLACEBO CONTROL IS NOT ETHICAL.

"An Algorithm for Evaluating the Ethics of Placebo-Controlled Clinical Trials,"
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