

the form and participating in the clinical trial are entirely voluntary (38,39,40,41).

- The consent form is reviewed and approved by an independent ethics committee, that is, the Institutional Review Board (IRB) (42,43). In other words, the fact that a body of experts that is independent from the study sponsor considers the clinical trial to be ethical, lends support to the specific argument that the placebo is ethical. Consent forms must also comply with the standards set forth in standards, such as those set forth by the Nuremberg Code (44), the Declaration of Helsinki (45,46), and the Belmont Report (47).
- Placebo groups are not without any kind of treatment. Placebo groups may receive treatment in the form of BSC or palliative

care. In commentary about oncology clinical trials, Daugherty et al. (48) wrote that, “[f]or the trial to be ethical, patients assigned to the placebo arm must also receive best supportive care . . . clinical trials that include best supportive care should carefully delineate the elements of such care, including consultation with appropriate experts.”

- Placebos do not have toxic effects because they are manufactured from inert ingredients (49). In contrast, study drugs often produce adverse drug reactions.
- The FDA has recognized a clinical trial study design that includes an *early escape* (50). Clinical trials in oncology, for example, have a number of endpoints, such as disease progression and survival time. Disease

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