



**Definition of a Quality Clinical Trial  
Position Statement**  
**Reaffirmed by the ASCO Board of Directors, March 2005**

The American Society of Clinical Oncology (ASCO) states that a quality clinical trial must involve the following criteria:

1. A written protocol, which includes the following elements: trial design and scientific justification, criteria for inclusion and exclusion, outcome measures, statistical analysis plan, conflicts and other ethical controls, and publication policy;
2. Scientific review of the protocol by a group of independent, qualified experts; and
3. Review and approval of the trial by a qualified institutional review board (IRB).