Message from the Pharmaceutical Sciences Committee Co-Chair:

With the availability of biosimilars, SWOG has taken the initiative to address the use of biosimilars in research protocols. There are two major categories of biosimilars: interchangable vs non-interchangable and the field is rapidly evolving which makes it challenging for SWOG to keep information updated in a timely manner when dealing with national communication and approval process. SWOG elected to use the major organization guidelines (ASCO and NCCN) to set the standards and entrust the institution's drug formulary governing body to come up with the institutional standard operation procedures (SOP) to guide for the product selection. For the investigator sites that do not have a drug formulary infrastructure or SOP, one can use the organizational guidelines to make the selection. SWOG used ASCO and NCCN as the primary sources of information and came up with the recommendation statement below that was approved in October 2015 for insertion in the protocol.

The standard language is: "White blood cell growth factors, including biosimilars, must be used per ASCO guidelines (<a href="http://jco.ascopubs.org/content/24/19/3187.full">http://jco.ascopubs.org/content/24/19/3187.full</a>) and NCCN Guidelines Myeloid Growth Factors (<a href="http://www.nccn.org/professionals/physician\_gls/pdf/myeloid\_growth.pdf">http://www.nccn.org/professionals/physician\_gls/pdf/myeloid\_growth.pdf</a>)."

The SWOG Pharmaceutical Sciences Committee will continue to monitor the evolving field of biosimilar utilization and work with SWOG leaderships to provide recommendations to address the use of biosimilars in protocol development and execution.