

**MEMORANDUM**

**TO:** Members of SWOG  
**FROM:** SWOG Operations Office  
**DATE:** November 1, 2020  
**SUBJECT:** Policy Revisions

The following SWOG policies have been revised as summarized below. These and all policies can be viewed and printed from the Group's web site at <https://www.swog.org/about/policies-procedures>.

Policy Revision Summation

**Policy 2 Constitution/Bylaws**

This policy was revised to update the definition of a Special Member.

**Policy 38 Dosing Principles for Patients on Clinical Trials**

A lack of consistency among site investigators was identified in their creatinine clearance estimations for patient eligibility assessments and dosing, dose rounding, and dose recalculation for significant weight change. Most of these occurrences were due to the sites using their own institutional policy and/or software management systems that have different set-ups. These events had resulted in protocol violation, rebuttal from site regarding patient eligibility, and patient safety issues. Based on task force findings and consultation with our NCI pharmacist liaison, the Pharmaceutical Sciences team revised the policy. Below is a summary of the changes:

- Elevated Dose Rounding as a subsection of I.3 and added additional detailed content.
- Updated the dose modification language in the new I.4 of the policy and adjusted “last dosing weight” to “last body weight used for dosing calculation” for clarity.
- Clarified the use of II.2 that the creatinine clearance calculation procedure is appropriate for both drug dosing and end organ function assessments for subject eligibility and post-enrollment.
- Changed the title of the policy from “Dosing Principles for Patients on Clinical Trials” to “Research Calculations for Clinical Trials”.
- Mandated the use of the online calculators in “Tools of the Trade” on the CRA Workbench for BSA and creatinine clearance estimation for protocol eligibility and post-enrollment. Links for the calculators have been added to Policy 38.