## SOP 8: Reviewing and Amending Standard Operating Procedures

### Overview:

1. The Division of Cancer Prevention (DCP) Consortia 2012 Standard Operating Procedures (SOPs) are written standard procedures that describe the responsibilities of Consortium Lead Organizations (CLOs) and Participating Organizations (POs) participating in DCP chemoprevention studies linked with the Consortia 2012 award date.
2. The DCP Consortia 2012 SOP documents are located on the Consortia for Early Phase Prevention Trials page of the DCP website at <http://prevention.cancer.gov/clinical-trials/clinical-trials-management/2012-consortia-early-phase>.
3. The CLO Site Coordinator is responsible for requesting approval from DCP to amend the SOPs when an amendment is warranted, for overseeing the review and amendment of the SOPs, and for submitting any amendments to DCP for approval.
4. The DCP Consortia 2012 SOPs:
	* + 1. Require review by DCP annually and may be updated more frequently when necessary, with the latest version of the SOPs superseding earlier versions;
5. Are to be adopted by the CLO and PO sites as written unless they are in direct conflict with local institutional policy. If this is the case, the CLO may amend the applicable SOPs only after obtaining approval from DCP;
6. Become effective ten (10) business days after posting to the DCP website, unless either implemented sooner by the CLO or amended by the CLO with DCP’s approval.

### Responsibilities:

The CLO Site Coordinator will:

1. Review the DCP SOPs annually or as updated by DCP to determine if they are compatible with the Consortium’s local institutional policy.
2. Review the DCP SOPs with the applicable PO Principal Investigators (PIs) and Site Coordinators to determine if there is a need to amend the SOPs.
3. Collect all amendment requests from the CLO and PO sites and electronically submit them as a package to the DCP Protocol Information Office (NCI\_DCP\_PIO@mail.nih.gov) and the DCP Help Desk (dcphelpdesk@dcpais.com).

The submission package will include:

* 1. A cover letter requesting the changes to the SOPs and explaining the rationale for the requested changes;
	2. The ‘clean’ copy of the revised SOPs with a ‘Site Version Date’ in the footer of the documents;
	3. The ‘tracked changes’ copy of the revised SOPs with the ‘Site Version Date’ in the footer of the documents.
1. Communicate DCP’s decision regarding the amended SOPs to all applicable CLO and PO staff.
2. Add the ‘Effective Site Version Date’ to the footer of the amended DCP SOPs once the amendments are approved by DCP.
3. Distribute the DCP-approved amended SOPs to all applicable CLO and PO staff for their use.

### Documentation Requirements:

1. Maintain the amended DCP Consortia 2012 SOPs on file at each site. DCP SOPs that have been amended by the Consortia sites are not posted on the DCP website.

### Additional Information:

Refer to the [DCP Acronym List](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/DCP-Acronym-List.docx) to see the description of commonly used acronyms in this SOP.

**Please send questions and comments to the DCP Help Desk at:
1-844-901-4357 or** **dcphelpdesk@dcpais.com**