Division of Cancer Prevention

Revision or Amendment Submission Checklist

For DCP Chemoprevention Studies

# DCP definition of a revision and amendment:

Revisions are changes made to the protocol and/or additional documents prior to DCP final approval.

Amendments are changes made to the protocol and/or additional documents after DCP final approval

# Checklist:

\_\_\_ A cover letter stating all the changes to the protocol, identified by section number, with change rationale provided.

\_\_\_ A point-by-point response to the Consensus Review, Concurrence Review, or Amendment request, if this submission is in response to a DCP or FDA request. **Note:** The cover letter and response memo can be combined.

\_\_\_ A new version date on the title page of the protocol. This version date must be current and different from any previous version of the protocol. The version date of the protocol and the informed consent form must match. A new version number must also be included. **A new version number is not needed in the following situations:** (1) Protocol Revision that was previously withdrawn or (2) Protocol Amendment that was previously withdrawn or disapproved.

\_\_\_ A clean copy of the protocol and informed consent form, including all appendices listed in the Table of Contents. N**ote:** The informed consent form must accompany each new version of the protocol.

\_\_\_ A tracked changes or highlighted copy of the protocol, informed consent form, and appendices listed in the Table of Contents

\_\_\_Any additional documents that have been revised/amended should be submitted with clean and tracked changes version. **Note**: If these are not listed in the Table of Contents, these documents do not need to be submitted unless they are being revised/amended. There should be an updated version date on the documents. Additional documents may include:

* Recruitment, Retention, and Adherence Plan
* Pharmacokinetic Biomarker Method Development Report
* Case Report Forms (CRFs)
* Budget

Submit revisions and amendments to PIO Document Submission System website at [https://applications.prevention.cancer.gov/pio-cts/dsw/](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2Fapplications.prevention.cancer.gov%2Fpio-cts%2Fdsw%2F__%3B!!PfbeBCCAmug!m5SNYbAdjjWBM6KrGGgrkuu3JsHtxoR6PgsjMbpcNkTtFnC5SBrFQKA0Ls4BfuMcyL-TVoXqaV5BYbOHLqSlsRSJxQ%24&data=05%7C02%7Cjennifer.pak%40nih.gov%7Cfd51a618d5874d61748608dc5fd9afd9%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C638490635765739448%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=X57PZRAcBalhhKdPBZpA253BgC5%2BFCKmrRvnJ%2FYLs%2F0%3D&reserved=0). All users must first create an account by contacting IMS at dcp-pio-cts-support@imsweb.com.

If you have any questions regarding the content or the process of the submission, please contact the DCP PIO at NCI\_DCP\_PIO@mail.nih.gov or 240-276-7130. If you are having any technical issues with your account or website, please contact IMS at dcp-pio-cts-support@imsweb.com.