DCP CONSORTIA 2012

STUDY CLOSEOUT CHECKLIST

| **Task#** | **Study Close-out Tasks**  | **Target Completion Timeline** | **Status** | **Instructions**  | **Site Comments** |
| --- | --- | --- | --- | --- | --- |
| 1. | Discuss study closeout requirements and study-specific issues with DCP Medical Monitor, Scientific Monitor, and Nurse Consultant prior to initiating study closeout activities |  | [ ]  Yes [ ]  No [ ]  N/A |  |  |
| 2. | Verify all participants are off study at all accruing sites |  | [ ]  Yes [ ]  No [ ]  N/A |  |  |
| 3. | Submit a [Protocol Status Update Form](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/protocol_status_update_form.docx) to the PIO |  | [ ]  Yes [ ]  No [ ]  N/A | Report Study Status as ‘Completed’ or ‘Administratively Completed’ |  |
| 4. | Complete CLO/PO data entry  |  | [ ]  Yes [ ]  No [ ]  N/A | Complete entry of all clinical data and resolve all open data queries, including open queries in AQuIP OARS |  |
| 5 | Complete CLO/PO data QA review(s) |  | [ ]  Yes [ ]  No [ ]  N/A |  |  |

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| --- | --- | --- | --- | --- | --- |
| 6. | Complete Close-out visits at POs  |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to [SOP 14 - CLO Monitor Instructions for Conducting Closeout Visits](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP14-Closeout-Visits.docx) for detailed instructions |  |
| 7. | Complete CLO closeout visit performed by DCP Monitoring Contractor  |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per DCP and CLO-specific procedures. Refer to [SOP 9 - Site Preparations for Monitoring Visits and Quality Assurance Audits](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP9-Site-Preparations-QA-Audits.docx), and [SOP 14 - CLO Monitor Instructions for Conducting Closeout Visits](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP14-Closeout-Visits.docx) for detailed instructions.  |  |
| 8. | Complete research lab(s) analyses and upload results to database of record or other data storage system |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per CLO-specific procedures |  |
| 9. | Clean and audit database of record in preparation for analysis and database lock |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per CLO-specific procedures  |  |
| 10. | Notify Medical Monitor, Scientific Monitor, and Nurse Consultant of intent to unblind the study and request approval (if applicable) |  | [ ]  Yes [ ]  No [ ]  N/A |  |  |

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| --- | --- | --- | --- | --- | --- |
| 11. | Unblind the study per Medical Monitor approval (if applicable) |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per CLO and Consortia-specific proceduresNotify Medical Monitor, Scientific Monitor, and Nurse Consultant when the study is unblinded |  |
| 12. | Deliver final and complete data set(s) to Study Statisticians for analysis |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per CLO-specific procedures |  |
| 13. | Complete final statistical analyses. |  | [ ]  Yes [ ]  No [ ]  N/A | Complete this task per CLO-specific procedures |  |
| 14. | Complete database lock  |  | [ ]  Yes [ ]  No [ ]  N/A | Database lock should not be completed until the final monthly MDS Report is reviewed and there are no further questions or queries to resolveNOTE: Submission of the monthly MDS Report to DCP is no longer required. |  |
| 15. | Submit draft manuscript to the DCP PIO for review |  | [ ]  Yes [ ]  No [ ]  N/A |  |  |
| 16. | Submit notice of the Study Closure or Study Completion as required to the IRB of Record, i.e. local IRB or CIRB |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to the local IRB or CIRB requirements for instructions regarding this task |  |
| 17. | Submit final datasets for clinical data, biomarker data, other study-specific data and documentation to DCP |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to [SOP 13 – Site Preparations for Study Closeout, Appendix A and Appendix D](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) for detailed instructions  |  |
| 18. | Review NIH policy for Genomic Data Sharing, and prepare data and documentation for genomic data submission |  | [ ]  Yes [ ]  No [ ]  N/A | This task is required only for those studies collecting genomic dataRefer to [SOP 13 – Site Preparations for Study Closeout, Appendix C](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) for detailed instructions  |  |
| 19.  | Submit file of Participant Responses to Informed Consent Specimen and/or Information Use Questions to DCP  |  | [ ]  Yes [ ]  No [ ]  N/A | This file should be submitted as an end of study dataset as specified in [SOP 13 – Site Preparations for Study Closeout, Appendix A and Appendix B](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) |  |
| 20. | Inform the biospecimen repository at Frederick National Laboratory for Cancer Research (FNLRC) of intent to submit biospecimens |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to [SOP 13 – Site Preparations for Study Closeout, Appendix B](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) for detailed instructions  |  |
| 21 | Submit the Materials Transfer Manifest for Biospecimen Submission (Manifest) to DCP and the FNLCR |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to [SOP 13 – Site Preparations for Study Closeout, Appendix B](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) and [SOP13c - Materials Transfer Manifest for Biospecimen Submission](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13c-C2012-Material-Transfer-Manifest.xls) for detailed instructions |  |
| 22. | Submit biospecimens to the Central Repository at FNLCR as directed by DCP |  | [ ]  Yes [ ]  No [ ]  N/A | Refer to [SOP 13 – Site Preparations for Study Closeout, Appendix B](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13-Site-Prep-Closeout.docx) for detailed instructions  |  |
| 23. | Receipt of DCP approval of the draft manuscript |  | [ ]  Yes [ ]  No [ ]  N/A | The final publication and/or notification of the publication should be submitted to the DCP PIO when received by the CLO |  |

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 Checklist.