## SOP 13: Site Preparations for Study Closeout

### Overview:

1. Participating Organizations (POs) are responsible for meeting all study obligations as part of study closeout.
2. The Consortium Lead Organization (CLO) will perform study close-out activities to confirm that all study obligations have been met and all final tasks associated with the study are complete.

### PO Responsibilities:

The PO Site Coordinator is responsible for coordinating the following closeout tasks in a timely manner:

1. All regulatory documents, including all required IRB/CIRB approvals, are current and on file.
2. The local IRB has been notified that all participants are off study according to institutional requirements.
3. An original or a certified copy of the original, signed and dated informed consent form(s) is on file for each participant.
4. All required logs and documentation for enrollment, screening, monitoring and/or auditing visits, protocol deviations, and SAEs are current and available.
5. Documentation is present in each participant’s record indicating that study participation has ended, and the participant is off study.
6. There are no adverse events or serious adverse events that require further follow-up for any participant.
7. All paper and/or electronic case report forms for each participant have been completed.
8. All data entry, data queries, and quality assurance (QA) activities in the database of record are complete.
9. All Drug Accountability Record Form(s) (DARFs) have been reconciled.
10. The research specimen log(s) and/or research specimen management system(s) is current.

### CLO Responsibilities:

The CLO Lead Site Coordinator is responsible for conducting and coordinating study closeout tasks within the timeframes outlined in the Consortium contract. The CLO Lead Site Coordinator will:

1. Verify all participants are off study at all accruing sites.
2. Submit the [Protocol Status Update Form](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/protocol_status_update_form.docx) to the DCP Protocol Information Office (PIO).
3. Verify all CLO/PO data entry is complete.
4. Complete the CLO/PO data QA review(s).
5. Complete the Closeout visits at the POs.
6. Ensure the DCP Monitoring Contractor is notified of the PO study closeout visit dates and has conducted the study closeout visit at the CLO.
7. Ensure that the research lab(s) analyses have been completed and the results have been uploaded to the database of record or other storage.
8. Clean and audit the database of record in preparation for analysis and database lock.
9. Notify the Medical Monitor and Scientific Monitor of the intent to unblind the study and request approval, if applicable.
10. Unblind the study upon approval by the Medical Monitor, if applicable (see [Appendix D](#AppendixD)).
11. Deliver all required final and complete datasets to the Study Statisticians.
12. Ensure that the final statistical analyses have been completed.
13. Complete database lock.
    1. Database lock should not be completed until the final monthly MDS Report is reviewed and there are no further questions or queries to resolve.
    2. Submission of the monthly MDS Report is no longer required.
14. Ensure that the draft manuscript is submitted to the DCP PIO, Medical Monitor, Scientific Monitor, and Nurse Consultant per contract requirements.
15. Submit the notice of the Study Closure or Study Completion as required to the IRB of Record, i.e. the local IRB or CIRB.
16. Verify the DCP Regulatory Contractor and/or the responsible party has complied with the NIH Office of Biotechnology Activities (OBA) reporting requirements for the study, if applicable, [http://osp.od.nih.gov/office‐biotechnology‐activities/biosafety/nih‐guidelines](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines).
17. Submit the final clinical, biomarker, unblinding, and other study-specific datasets to DCP (see [Appendix A](#AppendixA) and [Appendix D](#AppendixD)).

a. Submit other required data not collected in the database of record (biomarker data, individual surveys, etc.) and documentation (data dictionary) to DCP (see [Appendix A](#AppendixA)).

1. For those studies collecting genomic data, review the NIH policy for Genomic Data Sharing, and prepare data and documentation for genomic data submission (see [Appendix C](#AppendixC).)
2. Inform the biospecimen repository at the Frederick National Laboratory for Cancer Research (FNLCR) of the CLO’s intent to submit biospecimens.
   1. Submit the Material Transfer Manifest for Biospecimen Submission to the FNLCR and to DCP (see [Appendix B](#AppendixB) and [SOP13c: Material Transfer Manifest for Biospecimen Submission](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13c-C2012-Material-Transfer-Manifest.xls)).
   2. Submit biospecimens to the FNLCR as directed by DCP (see [Appendix B](#AppendixB)).
3. Verify receipt of DCP’s approval of the draft manuscript.

a. The final publication and/or notification of the publication should be submitted to the DCP PIO when received by the CLO.

### Documentation Requirements:

Each PO and CLO is responsible for maintaining all study records, including source documentation, case report forms, laboratory data, pharmacy documentation, regulatory documents, and study communications in a secure manner.

1. Study records will be accessible for inspection by authorized National Cancer Institute/Division of Cancer Prevention (NCI/DCP) representatives, the local IRB and CIRB, Food and Drug Administration (FDA) personnel, and/or any drug company supporting the study.
2. If the study is conducted outside of the United States, additional requirements may apply that are specific to the country of the site(s) participating in the study.
3. The study records must be maintained and accessible as specified in the study protocol.
4. The NCI/DCP will be notified prior to the planned destruction of any study materials.

### 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**](mailto:dcphelpdesk@dcpais.com)

**Appendix A**

**Consortia 2012**

**Final Dataset and Documentation Requirements**

**General Guidelines**

1. The Consortia Lead Organization (CLO) will submit study-specific datasets, data dictionaries and other documentation for each study as directed by DCP and/or as specified in the Consortia contract.
2. Digital delivery of the deliverables (listed below) is required.

1. All deliverables will be submitted via a secure managed file transfer.

2. A member of the DCP Study Closeout Team will contact the CLO to provide instructions and assistance for the secure transfer of the required materials.

3. A completed Final Dataset and Documentation Submission Summaryshould be submitted with the datasets and documentation. (See [SOP13b: Final Dataset and Documentation Submission Summary](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13b-C2012-Final-Data-Set.pdf))

4. All deliverables and related documents should be organized for submission as a single zip file.

1. The final datasets and related documentation should be submitted to DCP within 120 calendar days after completion of the study.
   1. DCP will notify the Consortium PI and study staff of the expected due date for submission of final datasets and documentation.

2. Final biomarker data, and biomarker and other laboratory study analyses may be submitted after the expected due date with prior approval by DCP.

D. Analytic and raw datasets of the final de-identified data from each study and related study documents will be posted to the Cancer Data Access System (CDAS) to provide access to these data to the research community. Please see <https://cdas.cancer.gov/eppt/> for additional information.

**Deliverables**

* 1. Final MDS Report

1. The final MDS Report should be prepared from the locked data for the study.

2. The final MDS Report and the code used to prepare the MDS Report should be submitted with the study-specific datasets so that the final MDS Report can be replicated as needed.

* 1. The Final MDS Report should also have been delivered to DCP as part of the regular monthly MDS submission.
  2. Study-specific Datasets and Documentation

1. Datasets are required for all clinical data, biomarker data, and other study-specific data used for analyses.
   1. Datasets should be a copy of the final, complete, cleaned, audited and locked data used for analysis. These datasets should include raw data, derived data and/or data that has been processed by the study site.
   2. Each dataset should include any descriptive and/or administrative information considered pertinent to the subsequent use of these data.
   3. The output file from the integrity check for each dataset should be submitted to confirm the intended transfer of the datasets.
2. Data are to be submitted as either SAS datasets (preferred) or CSV files.

3. Datasets prepared from study-specific questionnaires, informed consent specimen use questions, participant-specific unblinding information and other data should be submitted as follows:

4.1 Submit these data as one of the final clinical datasets if these data are included in the database of record.

4.2 Submit these data as individual datasets or spreadsheets if these data are collected outside of the database of record.

1. Documentation of the analysis and/or analytic code or programs should be submitted with the dataset(s).
2. The latest approved versions of the protocol, the CRFs or SVAR, the Schedule of Forms, the CDE Spreadsheet (as appropriate), and other forms and questionnaires should be submitted with the datasets. The version number and/or version date should be noted within each document.
   1. CRFs, other forms and questionnaires should be submitted in Word or PDF format only. A list or version index of the CRFs or SVAR tabs should be provided.
   2. An explanation and/or screenshots demonstrating how the data were collected should be submitted.

5.3 Data obtained from other than a CRF or SVAR should be identified in the dataset. The source of these data should be specified.

6. Study-specific Notes-To-File that are pertinent to the data collection, review and/or analysis of the data should be submitted as supporting documentation.

* 1. Data dictionaries

1. A data dictionary should be submitted for each SAS dataset.

1.1 Contents of the dictionary should include (at a minimum) the variable name, Label/Question, Label Description, Text Format and CDE ID#. See SOP13b, Attachment A for an example of a data dictionary.

**Appendix B**

**Consortia 2012**

**Biospecimen Submission Requirements**

**Overview**

Requirements for study-specific biospecimen management, including their collection, shipping, storage and banking, are defined in Section 10 of each study protocol.

Centralized storage and distribution of biospecimens required at the end of a study will be managed by the Frederick National Laboratory for Cancer Research (FNLCR).

Biospecimens designated for centralized storage and distribution must be confirmed as consented for future use prior to forwarding these specimens to FNLCR. Any biospecimens that are lacking this consent should not be shipped to FNLCR and should be managed per institutional requirements. A final dataset of each participant’s responses to the questions regarding specimen and information use included in the study’s informed consent is to be submitted with the end of study datasets. This dataset may be shared with the FNLCR to facilitate processing and future use of the biospecimens.

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Prior to the shipment of biospecimens, a webinar will be held by FNLCR with the responsible institution to discuss the specifics of the study’s specimen collection, review supply and shipment instructions, and develop a timeline for related tasks and activities. Supplies and related materials will be provided by FNLRC to ensure the proper packaging and transportation of specimens to the FNLCR repository.

The FNLCR Head of Bioprocessing and Trial Logistics is responsible for general oversight of this process, laboratory administration, shipping supplies, and specimen database inquiries. When biospecimens are ready to be shipped, please notify DCP at [C2012Biospecimens@mail.nih.gov](mailto:C2012Biospecimens@mail.nih.gov) and also contact:

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**Biospecimen Data Submission Requirements**

A final dataset of each participant’s responses to the questions in the informed consent regarding study-specific specimen and information use is to be submitted with end of study datasets as specified in [Appendix A](#AppendixA).

An electronic item-level Material Transfer Manifest (Manifest) is to be submitted prior to shipment of any biospecimens to FNLCR. The data fields listed below should be provided for each specimen listed on the Manifest. Please note these are the minimum data required for each biospecimen submitted. Additional data may be required and/or requested depending on the specialized needs of the project and/or protocol requirements.

The required data fields are:

* Verification: All biospecimens listed on this Manifest have been reviewed as consented for future use
* Signature and date of shipper or designated representative
* Item Number
* Protocol Number
* Current Label
* Center
* Hemolyzed
* Subject ID
* Date Drawn
* Material Type
* Material Modifiers
* Date Processed
* Label Status
* Volume
* Volume Unit
* Box
* Row
* Column

A template for the Manifest, including a description of each required data field, is provided in [SOP13c: Material Transfer Manifest for Biospecimen Submission](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13c-C2012-Material-Transfer-Manifest.xls). The Manifest should be submitted to FNLCR at [diazmayoraln@mail.nih.gov](mailto:diazmayoraln@mail.nih.gov) and DCP at [C2012Biospecimens@mail.nih.gov](mailto:C2012Biospecimens@mail.nih.gov) at least 48 hours to prior to shipment of the listed biospecimens.

**Packaging and Shipping**

Supplies are provided by FNLCR for frozen, chilled and room temperature shipments, as required. The supplies will include packaging, instructions, points of contact, shipping address, and prepaid courier documents.

Biospecimens should be shipped with a copy of the Manifest and a packing slip in each package. The shipping address for these materials is noted on the Manifest. Details regarding completion of the Manifest and packing slip will be reviewed during the pre-shipment webinar with the responsible institution.

**Appendix C**

**Consortia 2012**

**Instructions for Submission of Genomic Data**

**General Guidelines**

In order to comply with the National Cancer Institute Genomic Data Sharing (GDS) policy, the Office of Data Sharing (ODS) recommends extramural investigators refer to the following links for the NIH policy for genomic data sharing and the requirements for submitting genomic data to NIH, NCI.

General Data Sharing Information

<https://cbiit.cancer.gov/data-sharing>

Genomic Data Sharing Policy

[https://osp.od.nih.gov/scientific-sharing/policies](https://osp.od.nih.gov/scientific-sharing/policies/)

Extramural Data Submission

<https://cbiit.cancer.gov/extramural-grantees-submitting-data>

**Appendix D**

**Consortia 2012**

**Study Unblinding Data Requirements**

**General Guidelines**

1. Treatment/study intervention assignments for all randomized participants are to be unblinded, whether or not the randomized participant received the study agent/intervention.
2. No information identifying a participant should be included in the dataset.
3. To facilitate the integration of data across all Consortia 2012 studies, the use of CDEs in reporting these data are required. Only valid values from the CDE list of values for the study should be used.
4. Unblinding data should be submitted as either study-specific SAS datasets (preferred), CSV files, or in a spreadsheet format. (See [SOP13d: Study Unblinding Worksheet](https://prevention.cancer.gov/sites/default/files/uploads/clinical_trial/SOP13d-C2012-Study-Unblinding-Worksheet_0.xls))
5. An unblinding key will be provided to the DCP Regulatory Contractor to support their review of Consortia 2012 safety data.

**Data Reporting Requirements**

The following data must be submitted to document study unblinding. All data are required to ensure an accurate association between the participant and the assigned intervention.

1. DCP Protocol Number
2. Registering Consortium Code
3. Registering Institution Name
4. Registering Institution Code
5. Participant ID (PID)
6. Participant Birth Date
7. Randomization Number (if applicable)
8. Treatment Assignment Code (TAC)
9. Agent Name
10. Agent Dose
11. Agent Units
12. Agent Frequency

A “Comments” column can be added to the Study Unblinding Worksheet to use when needed to report any additional information about a participant’s unblinding. For example:

1. The TAC is changed from the TAC assigned at registration (for non-randomized studies) or randomization. The comments should include the date the TAC was changed and the reason for the change.
2. Institution or study-specific practices for data reporting require clarification by the study site staff.