

STATEMENT OF WORK – YEAR 1 (Base Year)

Independently and not as an agent of the government, the Contractor shall be required to furnish all the necessary services, qualified personnel (including skilled nursing and genetic counseling personnel), material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work identified herein. Types of support to be provided by the Contractor in the conduct of studies may vary. The time line or schedule for support activities will be specified by the NCI Contracting Officer Representative (COR) based on the study. The Contractor shall inform the NCI COR of any unforeseen circumstances that may delay timely completion or progress of study activities. All study activities, documents, and procedures must be approved by the COR prior to implementation. The Contractor shall perform some or all of the following support activities as may be specified by the NCI COR in the conduct of each study:

A. Study Initiation and Liaison

1. Determine parties whose cooperation and approval is necessary for implementation of the study (e.g., federal or state agencies, universities, hospitals, medical offices, laboratories, other NCI Contractors, etc.).
2. Arrange for communication and meetings between the NCI research investigators and agents for those parties whose cooperation or approval is needed.
3. Attend such meetings, provide background information required, and take appropriate action on recommendations as applicable. Document proceedings and action items as requested by NCI staff.
4. When multiple institutions are involved in a multi-center study, Support the Clinical Genetics Branch (CGB), NCI in developing procedures to insure that the investigation is being conducted in a standardized manner at all sites.
5. Support the CGB, NCI in obtaining information required to determine various capabilities; including but not limited to, potential collaborating institutions, potential collaborating, and eligible study subjects.
6. Support the CGB, NCI in making arrangements for document translations as necessary to initiate studies in foreign settings or to enroll family members from foreign sites.
7. Support the CGB, NCI during their evaluation of collaborating centers, institutions or companies, as well as their evaluation of financial and administrative matters related to the collection of data and biological specimens.
8. Support in the development of protocols and completion of forms as may be required for various committees, such as Institutional Review Boards. Attend such committee meetings if requested by the COR (or a designated representative, hereafter referred to only as the COR).

B. Development of Study Materials and Procedures

1. Support the CGB, NCI in preparing, pretesting, and producing data collection forms (e.g., abstract forms, follow-up forms, coding forms, questionnaires and exposure assessment forms, bio-specimen collection and processing forms, tracking forms, etc.). Questionnaires may be either paper, machine readable, or computer-assisted.
2. Support the CGB, NCI in preparing training programs and materials for abstractors, interviewers and other study personnel. Conduct training for new staff in a timely manner and update training for all staff as needed, but not less than annually.
3. Support the CGB, NCI in preparing procedure manuals for nurses, genetic counselors, research assistants, phlebotomists, abstractors, coders, interviewers, tracers, supervisors, data editors, and other personnel as needed.
4. Support the CGB, NCI in preparing procedure manuals for the collection of biological specimens, shipment of biological specimens, submission of specimens to repositories, and tracking of specimens and laboratory results.
5. Support the CGB, NCI in preparing manuals for obtaining and handling medical records, pathology specimens and reports, submission of pathology specimens for review, and collection of death certificates or cause of death. This includes coordinating systematic reviews and coding of reports or of surgical pathology specimens (i.e., central pathology review) by appropriate nosologists, clinicians or pathologists.
6. Support the CGB, NCI in preparing and updating manuals of usual operating procedures relative to evaluating, managing and coordinating follow-up of members of high-risk families.
7. Support the CGB, NCI in preparing nursing assessments and plans for clinical evaluation of individuals at high risk of cancer because of family history or specific exposures.
8. Contribute to preparation of newsletters, brochures, and other large mailings for families participating in ongoing studies.
9. Support the CGB, NCI in the preparation of study-specific packages for OMB, IRB, and/or OHSR [the Office of Human Subjects Research, formerly known as OPRR] reviews.
10. Translate data collection instruments or manuals into appropriate languages for foreign studies. This may include, at the request of the COR, reverse translation of

these materials back into English, to insure that the meaning and intent of the original document has been preserved.

11. Coordinate the collection, processing, storage and shipment of biological specimens, tracking of samples sent to collaborating laboratories as well as sample test results. Serve as liaison between the COR and the staff of various CGB and DCEG support laboratories and bio-specimen repository facilities.
12. As required for the CGB, NCI to conduct its studies, arrange for the laboratory analysis of biological materials collected from study participants, preparing subcontracts as necessary to accomplish this goal. Assess the capabilities, quality control procedures, and performance abilities of various laboratory facilities. Monitor quality control of ongoing specimen analyses. Integrate laboratory test results into study databases.
13. Since many of these activities will be essentially the same form across all disorders and all sub-studies, systems should be designed in a flexible, modular, generic fashion, so that they may serve as standard shells or templates which will be readily modified for use in future studies.

C. Subject Identification, Selection, and Tracing

1. Identify study subjects who meet NCI criteria for being included in studies, particularly women, minorities, and children, as appropriate. Plan the method of identification of study subjects and make recommendations on the feasibility of alternative sampling designs. Typical study subjects include:
 - a. All members of families in which several members have a particular condition of interest identified by the investigators.
 - b. All patients with a newly-diagnosed relevant disorder occurring in a patient or family member with the appropriate genetic disorder.
 - c. Patients treated for an initial symptom who are being followed for the occurrence of cancers or other treatment-related outcomes of interest.
2. Support the CGB, NCI in tracing study subjects and locating them or their next of kin for interview, examination and/or collection of study-specific biological specimens.
3. Support the CGB, NCI in maintaining current contact information for study participants and their health care providers, updating existing computer records containing contact information in an ongoing fashion, and tracing selected family members who have been lost to follow-up.

D. Interview and Abstracting Data Collection

1. Support the CGB, NCI in obtaining the necessary permissions/consents and then interview subjects or their family members using mail, telephone, or in-person questionnaires. Verify a sample of completed questionnaires. Questionnaire content will be provided by the NCI COR and will be jointly modified, if necessary.
2. Abstract, photocopy, microfilm or computerize records (clinic or office medical records, hospital charts, vital records, job records, etc.). Maintain quality control over the abstracting or copying process. Verify the accuracy of an appropriately sized sample of abstracts (determined with the COR) by independent re-abstracting. Accuracy is will be monitored by the COR.
3. Procure death certificates from vital records departments. The Contractor shall be responsible for determining details of and payment for death certificate procurement. The Contractor shall also be responsible for complying with requirements regarding retention of such records in consultation with the COR.
4. Purchase other data (e.g., professional organization mailing lists), materials (e.g., specimen collection kits) and/or services (e.g., phlebotomy service, pathology/medical records) necessary for the completion of studies, as directed by the COR.
5. Support the CGB, NCI in validating exposure or disease histories obtained in interviews by obtaining copies of original records. This includes maintaining a management tracking system for the retrieval of such records.
6. Support the CGB, NCI in obtaining copies of imaging studies, radiographs, or other clinical tests (e.g. electrocardiograms) and the associated reports as needed for specific studies.
7. Oversee field activities that result in data collection.
8. Support the CGB, NCI in implementing management tracking systems that monitor the incoming flow of data, the editing of data, changing/modifying data, etc., to permit preparation of descriptive summary reports related to these activities.

E. Clinical Support Activities

1. Provide skilled nursing and genetic counseling support for family studies. This includes obtaining detailed family and personal medical histories, developing and updating pedigrees, educating and counseling patients, triaging inquiries regarding study participation, presenting inquiries and pedigrees at CGB IBMFS meetings for consideration of protocol eligibility, and providing clinical support to the NCI investigators.
2. Arrange admission (both Outpatient and Inpatient) to the NIH Clinical Center for those high-risk individuals and their family members identified by the COR or NCI investigator. If family members are unable/unwilling to travel to NCI, arrange for family members to be seen by Contractor and/or NCI personnel in local facilities as needed in the study.
3. Arrange for and coordinate clinical and research diagnostic studies and laboratory evaluation of NCI outpatients and study participants, both at the Clinical Center and in the patients' home communities, as directed by the COR or designated NCI investigators, at the patient's convenience. Provide information to the patients about all scheduled procedures and any necessary preparations. Answer clinical questions or direct them to the appropriate NCI investigator.
4. Support the CGB, NCI by arranging for collection of bio-specimens (including, but not limited to blood, tumor tissue, normal tissue, skin, urine, bone marrow, etc.) either at the Clinical Center or in the patients' home communities.
5. Obtain original pathology slides and blocks with associated pathology reports for review by study pathologist(s). Disperse to the appropriate study pathologist with appropriate clinical history and local pathology report(s). Maintain up-to-date inventory of requested, received, and dispersed slides and tissue blocks. Track results of pathology review, and code data for entry into computerized databases after approval by the NCI investigator(s).

F. Specimen Collection, Processing, and Shipment

1. Support the CGB, NCI by providing expertise in the arrangement and coordination of all aspects of biological sample collection, handling, transport, storage, distribution, analysis and information processing. Develop subcontracts as necessary to complete these tasks.
2. Support the CGB, NCI in collecting and safely delivering intact biologic specimens (blood, urine, tumor, etc.) in appropriate shipping containers and under appropriate shipping conditions to designated laboratories or investigators for storage and/or analysis. This includes transport of biologic specimens to and from international sites with necessary custom clearances. Shipping must be done in a

manner that will permit rapid and reliable tracking of specimens that go astray. Verify safe arrival of specimens to the destinations.

3. Arrange for specimen storage and/or standard laboratory tests or assays on biologic specimens (in one or several laboratories or repositories), as designated by the COR or NCI investigator(s).
4. Maintain an onsite repository of selected biological materials and specimens, as requested by the COR. These might include paraffin blocks, microscope slides, clinical photographs, etc., obtained from study participants. The contents of, and
5. Transfers into and out of this storage facility should be easily accomplished through computerized tracking tools.
6. Perform other support activities involving specimen collection, storage, and/or dispersal to laboratories as requested by the COR or NCI investigator(s).
7. Report to the COR all irregularities, delays, losses, deteriorations, unplanned defrostings, accidents, mishandlings, errors, discrepancies, and inefficiencies connected with any specimen collection, delivery, storage, or testing activity as soon as it becomes known to the Contractor.
8. Obtain all necessary laboratory reports of results or progress.
9. Interface with, use and program NCI's BSI-II bio-specimen repository data base. Monitor the status, and manage the utilization of biological samples collected from CGB study participants and stored in this system. Generate reports as requested by the COR. This software program and its attendant documentation will be provided by the Government.
10. Interface with, download and store data from the NIH Clinical Center medical information to the extent permitted by the NIH, particularly reports from Clinical Center Laboratories, the Department of Pathology, and the Diagnostic Imaging facility, as well as consultants within the NIH. Details of this activity will be developed when available.

G. Data Preparation

1. Develop or select disease, occupation, industry, demographic, geographic, and exposure coding schemes in consultation with NCI staff.
2. Code all data generated by CGB studies into computer readable form. Verify at least a 10 percent sample of the coding by independent re-coding. Summarize and describe the differences between the two sets of data. Accuracy is to be maintained at 98% level.

3. Support the CGB, NCI by developing documentation of codes used and listings of unusual or aberrant responses.
4. Enter coded information into appropriate computer databases. Verify all or at least a 10% sample (at the discretion of the COR) by data re-entry (e.g., double key entry), using a different data entry person. Summarize and describe the differences between the two data sets. Accuracy is to be maintained at 98% level.

H. Computer Programming and Data Processing

1. Use modifiable data management and tracking systems that can be applied across studies. Minimize creation of unique study-specific management and tracking systems. Such systems must be approved by the COR. Systems should be compatible with the Bio-specimen Inventory II, Laboratory Information System of the Core Genotyping Facility, FAIR/FAIRVIEW or others as appropriate and specified by the COR.
2. Provide capability of creating data sets with up to thousands of study subjects and tens of thousands of variables in SAS, STATA, SPSS, Excel, or other programs as requested by the COR. All data processing, storage, and transfer must be in compliance with US government standards of privacy and confidentiality.
3. Maintain adequate backup of study data and secure storage of backup media. Frequency of backup shall be determined by the Contractor and the COR.
4. Use the DCEG system FAIR/FAIRVIEW for the maintenance of family studies data. Ensure that nursing personnel and support research assistants all are trained in the use of FAIR/FAIRVIEW and have access to FAIR/FAIRVIEW. Provide pedigrees using PROGENY or other software as designated by the COR.

Note: FAIR/FAIRVIEW is a proprietary relational database software package developed for use by DCEG, NCI. The Government shall provide the FAIR/FAIRVIEW software for its use to the Contractor. The Contractor shall provide the appropriate personal computers and time for training of personnel to use FAIR/FAIRVIEW.

5. Enter coded information onto suitable computer devices. Verify entry by 100 percent re-keying (or a 10% sample at the discretion of the COR).
6. Prepare edit programs, edit data, and correct computer files where necessary. Describe findings in summary form.
7. Update files with follow-up data, error corrections, etc. as directed by the COR.
8. Prepare data sets for transfer to NCI computers, as specified by the COR.

9. At the direction of the COR, respond to priority requests and changes of resource allocations rapidly, by appropriate activities and use of personnel.

I. Study Monitoring, Quality Control, and Reporting

1. Document each step in a specific study and maintain, in an orderly arrangement, all relevant material so that any aspect of a study may be reviewed and evaluated by the NCI staff at any point in time. Involved are the following:
 - b. Type letters and prepare forms and other documents necessary in the conduct of a study.
 - c. Duplicate study documents when the original sources cannot be retained.
 - d. Maintain a filing system of all materials relevant to a particular study, cross-referenced in a manner so as to make all of the material easily accessible. These materials shall be maintained under security in accordance with requirements of the Privacy Act as it applies to Contractors. Data for family studies shall be maintained in accordance with requirements of a Certificate of Confidentiality.
 - e. Maintain a log of decisions made during each study that affect the design, conduct, or analysis. Each entry shall include a brief explanation and date of the problem, the decision made, and the name of the NCI staff member who authorized the change.
2. Support CGB, NCI in developing and using internal record-keeping procedures for assessing the progress and status of data collection, preparation and entry. These record systems may be paper files or computer systems.
3. Support the CGB, NCI by monitoring and documenting the performance and progress of any work done under subcontract in the performance of a study.
4. Support the CGB, NCI by developing quality control procedures for the handling of biologic specimens specific for the needs of each study.
5. Report verification rates, discrepancy rates, and error rates for data collection, preparation and keying following the schedule agreed upon with the COR. Any unusual problems shall be brought immediately to the attention of the COR.
6. Provide quarterly and final technical progress reports; and monthly budget reports.

J. Family Medical Record Room and Database Maintenance

1. Store the medical records of more than 1000 families (more than 10,000 individuals). Maintain storage system that makes misfiled records apparent.

2. Provide physical access to patient medical records within thirty (30) minutes by the COR and designated medical personnel 24 hours a day, 7 days a week.
3. Restrict access to the family medical records to authorized personnel. Any transport/delivery of records outside of the record room must be via secured or locked container. Maintain a tracking log of records that leave the medical record room. Insure that all Contract personnel who have access to these records have been satisfactorily trained with regard to issues of data privacy and confidentiality.
4. Add new family data to the existing computerized database (FAIR/FAIRVIEW) of records from high-risk families. The Contractor shall establish procedures to ensure that data are entered into FAIR/FAIRVIEW in a timely and accurate manner.
5. Maintain medical records with content and order as directed by the COR. File reports and other documents in the medical records within one business day of receipt.
6. Support the CGB, NCI in maintaining pathology slide and paraffin block collection and related databases.
7. Support the CGB, NCI in maintaining clinical photograph database. These may consist of both paper prints and digital images.
8. Support the CGB, NCI in maintaining photographic slides and prints in easily retrievable archival quality storage in the Medical Record Room.
9. Maintain referral/consult records as specified by the COR.

K. Transition - In

The Contractor shall submit a Transition - In Plan within 15 calendar days of award that describes the process, details, and schedule for providing an orderly transition during the Contract's Transition Term of 30 calendar days, in accordance with the guidance herein for all elements of the Statement of Work.

The objectives of the Transition Plan are: to minimize the impacts on continuity of operations; maintain communication with staff and affected communities; identify key issues; and overcome barriers to transition. The Contractor is responsible for performing due diligence to ensure that all the transition activities are identified, negotiated, and completed during the Transition Term. The Contractor shall establish a transition management team capable of providing overall management and logistical support of all transition activities. The Contractor shall develop a resource-loaded project management schedule compatible with predecessor contractor software (if different). Milestones and measurable commitments will be included in the schedule. The Contractor will regularly report status to the NCI at periodic meetings and through regular written reports.

STATEMENT OF WORK – (Option Years One through Four)

Independently and not as an agent of the government, the Contractor shall be required to furnish all the necessary services, qualified personnel (including skilled nursing and genetic counseling personnel), material, equipment, and facilities, not otherwise provided by the government, as needed to perform the work identified herein. Types of support to be provided by the Contractor in the conduct of studies may vary. The time line or schedule for support activities will be specified by the NCI Contracting Officer Representative (COR) based on the study. The Contractor shall inform the NCI COR of any unforeseen circumstances that may delay timely completion or progress of study activities. All study activities, documents, and procedures must be approved by the COR prior to implementation. The Contractor shall perform some or all of the following support activities as may be specified by the NCI COR in the conduct of each study:

A. Study Initiation and Liaison

1. Arrange for communication and meetings between the NCI research investigators and agents for those parties whose cooperation or approval is needed.
2. Attend such meetings, provide background information required, and take appropriate action on recommendations as applicable. Document proceedings and action items as requested by NCI staff.
3. When multiple institutions are involved in a multi-center study, develop procedures to insure that the investigation is being conducted in a standardized manner at all sites.
4. Support obtaining information required to determine various capabilities; including but not limited to, potential collaborating institutions, potential collaborating, and eligible study subjects.
5. Make arrangements for document translations as necessary to initiate studies in foreign settings or to enroll family members from foreign sites.
6. Negotiate and manage with collaborating centers, institutions or companies all financial and administrative matters related to the collection of data and biological specimens. This includes subcontracting, purchase of equipment, and other forms of compensation.
7. Support in the development of protocols and completion of forms as may be required for various committees, such as Institutional Review Boards. Attend such committee meetings if requested by the COR.

B. Development of Study Materials and Procedures

1. Prepare, pretest, and produce data collection forms (e.g., abstract forms, follow-up forms, coding forms, questionnaires and exposure assessment forms, bio-specimen collection and processing forms, tracking forms, etc.). Questionnaires may be either paper, machine readable, or computer-assisted.

2. Prepare training programs and materials for abstractors, interviewers and other study personnel. Conduct training for new staff in a timely manner and update training for all staff as needed, but not less than annually.
3. Prepare procedure manuals for nurses, genetic counselors, research assistants, phlebotomists, abstractors, coders, interviewers, tracers, supervisors, data editors, and other personnel as needed.
4. Prepare manuals for obtaining and handling medical records, pathology specimens and reports, submission of pathology specimens for review, and collection of death certificates or cause of death. This includes coordinating systematic reviews and coding of reports or of surgical pathology specimens (i.e., central pathology review) by appropriate nosologists, clinicians or pathologists.
5. Prepare and update manuals of usual operating procedures relative to evaluating, managing and coordinating follow-up of members of high-risk families.
6. Prepare nursing assessments and plans for clinical evaluation of individuals at high risk of cancer because of family history or specific exposures.
7. Contribute to preparation of newsletters, brochures, and other large mailings for families participating in ongoing studies.
8. Support in the preparation of study-specific packages for OMB, IRB, and/or OHSR [the Office of Human Subjects Research, formerly known as OPRR] reviews.
9. Translate data collection instruments or manuals into appropriate languages for foreign studies. This may include, at the request of the COR, reverse translation of these materials back into English, to insure that the meaning and intent of the original document has been preserved.
10. Coordinate the collection, processing, storage and shipment of biological specimens, tracking of samples sent to collaborating laboratories as well as sample test results. Serve as liaison between the COR and the staff of various CGB and DCEG support laboratories and bio-specimen repository facilities.
11. Arrange for the laboratory analysis of biological materials collected from study participants, preparing subcontracts as necessary to accomplish this goal. Assess the capabilities, quality control procedures, and performance abilities of various laboratory facilities. Monitor quality control of ongoing specimen analyses. Integrate laboratory test results into study databases.
12. Since many of these activities will be essentially the same form across all disorders and all sub-studies, systems should be designed in a flexible, modular,

generic fashion, so that they may serve as standard shells or templates which will be readily modified for use in future studies.

C. Subject Identification, Selection, and Tracing

1. Trace study subjects and locate them or their next of kin for interview, examination and/or collection of study-specific biological specimens.
2. Maintain current contact information for study participants and their health care providers, updating existing computer records containing contact information in an ongoing fashion, and tracing selected family members who have been lost to follow-up.

D. Interview and Abstracting Data Collection

1. Obtain the necessary permissions/consents and then interview subjects or their family members using mail, telephone, or in-person questionnaires. Verify a sample of completed questionnaires. Questionnaire content will be provided by the NCI COR and will be jointly modified, if necessary.
2. Abstract, photocopy, microfilm or computerize records (clinic or office medical records, hospital charts, vital records, job records, etc.). Maintain quality control over the abstracting or copying process. Verify the accuracy of an appropriately sized sample of abstracts (determined with the COR) by independent re-abstracting. Accuracy will be monitored by the COR.
3. Procure death certificates from vital records departments. The Contractor shall be responsible for determining details of and payment for death certificate procurement. The Contractor shall also be responsible for complying with requirements regarding retention of such records in consultation with the COR.
4. Purchase other data, materials, and/or services as directed by the COR.
5. Validate exposure or disease histories obtained in interviews by obtaining copies of original records. This includes maintaining a management tracking system for the retrieval of such records.
6. Obtain copies of imaging studies, radiographs, or other clinical tests (e.g. electrocardiograms) and the associated reports as needed for specific studies.
7. Oversee field activities that result in data collection.
8. Implement management tracking systems that monitor the incoming flow of data, the editing of data, changing/modifying data, etc., to permit preparation of descriptive summary reports related to these activities.

E. Clinical Support Activities

1. Provide skilled nursing and genetic counseling support for family studies. This includes obtaining detailed family and personal medical histories, developing and updating pedigrees, educating and counseling patients, triaging inquiries regarding study participation, presenting inquiries and pedigrees at CGB IBMFS meetings for consideration of protocol eligibility, and providing clinical support to the NCI investigators.
2. Arrange admission (both Outpatient and Inpatient) to the NIH Clinical Center for those high-risk individuals and their family members identified by the COR or NCI investigator. If family members are unable/unwilling to travel to NCI, arrange for family members to be seen by Contractor and/or NCI personnel in local facilities as needed in the study.
3. Arrange for and coordinate clinical and research diagnostic studies and laboratory evaluation of NCI outpatients and study participants, both at the Clinical Center and in the patients' home communities, as directed by the COR or designated NCI investigators, at the patient's convenience. Provide information to the patients about all scheduled procedures and any necessary preparations. Answer clinical questions or direct them to the appropriate NCI investigator.
4. Arrange for collection of bio-specimens (including, but not limited to blood, tumor tissue, normal tissue, skin, urine, bone marrow, etc.) either at the Clinical Center or in the patients' home communities.
5. Obtain original pathology slides and blocks with associated pathology reports for review by study pathologist(s). Disperse to the appropriate study pathologist with appropriate clinical history and local pathology report(s). Maintain up-to-date inventory of requested, received, and dispersed slides and tissue blocks. Track results of pathology review, and code data for entry into computerized databases after approval by the NCI investigator(s).

F. Specimen Collection, Processing, and Shipment

1. Provide expertise in the arrangement and coordination of all aspects of biological sample collection, handling, transport, storage, distribution, analysis and information processing. Develop subcontracts as necessary to complete these tasks.
2. Train phlebotomists and others who will be involved in bio-specimen collection. These individuals must be familiar with Universal Precautions required for the safe handling of potentially hazardous biological materials.
3. Collect and safely deliver intact biologic specimens (blood, urine, tumor, etc.) in appropriate shipping containers and under appropriate shipping conditions to

designated laboratories or investigators for storage and/or analysis. This includes transport of biologic specimens to and from international sites with necessary custom clearances. Shipping must be done in a manner that will permit rapid and reliable tracking of specimens that go astray. Verify safe arrival of specimens to the destinations.

4. Arrange for specimen storage and/or standard laboratory tests or assays on biologic specimens (in one or several laboratories or repositories), as designated by the COR or NCI investigator(s).
5. Maintain an onsite repository of selected biological materials and specimens, as requested by the COR. These might include paraffin blocks, microscope slides, clinical photographs, etc., obtained from study participants. The contents of, and transfers into and out of, this storage facility should be easily accomplished through computerized tracking tools.
6. Perform other support activities involving specimen collection, storage, and/or dispersal to laboratories as requested by the COR or NCI investigator(s).
7. Report to the appropriate COR all irregularities, delays, losses, deteriorations, unplanned de-frostings, accidents, mishandlings, errors, discrepancies, and inefficiencies connected with any specimen collection, delivery, storage, or testing activity as soon as it becomes known to the Contractor.
8. Obtain all necessary laboratory reports of results or progress.
9. Interface with, use and program NCI's BSI-II bio-specimen repository database. Monitor the status, and manage the utilization of biological samples collected from CGB study participants and stored in this system. Generate reports as requested by the COR. This software program and its attendant documentation will be provided by the Government.
10. Interface with, download and store data from the NIH Clinical Center medical information to the extent permitted by the NIH, particularly reports from Clinical Center Laboratories, the Department of Pathology, and the Diagnostic Imaging facility, as well as consultants within the NIH. Details of this activity will be developed when available.

G. Data Preparation

1. Develop or select disease, occupation, industry, demographic, geographic, and exposure coding schemes in consultation with NCI staff.
2. Code all data generated by CGB studies into computer readable form. Verify at least a 10 percent sample of the coding by independent re-coding. Summarize and

describe the differences between the two sets of data. Accuracy is to be monitored by the COR.

3. Develop documentation of codes used and listings of unusual or aberrant responses.
4. Enter coded information into appropriate computer databases. Verify all or at least a 10% sample (at the discretion of the COR) by data re-entry (e.g., key punch and verification), using a different data entry person. Summarize and describe the differences between the two data sets. Accuracy is to be monitored by the COR.

H. Computer Programming and Data Processing

1. Use modifiable data management and tracking systems that can be applied across studies. Minimize creation of unique study-specific management and tracking systems. Such systems must be approved by the COR. Systems should be compatible with the Bio-specimen Inventory II, Laboratory Information System of the Core Genotyping Facility, FAIR/FAIRVIEW or others as appropriate and specified by the COR.
2. Provide capability of creating data sets with up to thousands of study subjects and tens of thousands of variables in SAS, STATA, SPSS, Excel, or other programs as requested by the COR. All data processing, storage, and transfer must be in compliance with US government standards of privacy and confidentiality.
3. Maintain adequate backup of study data and secure storage of backup media. Frequency of backup shall be determined by the Contractor and the COR.
4. Use the DCEG system FAIR/FAIRVIEW for the maintenance of family studies data. Ensure that nursing personnel and support research assistants all are trained in the use of FAIR/FAIRVIEW and have access to FAIR/FAIRVIEW. Provide pedigrees using PROGENY, CYRILLIC, or other software as designated by the COR.

Note: FAIR/FAIRVIEW is a proprietary relational database software package developed for use by DCEG, NCI. The Government shall provide the FAIR/FAIRVIEW software for its use to the Contractor. The Contractor shall provide the appropriate personal computers and time for training of personnel to use FAIR/FAIRVIEW.

5. Enter coded information onto suitable computer devices. Verify entry by 100 percent re-keying (or a 10% sample at the discretion of the COR).
6. Prepare edit programs, edit data, and correct computer files where necessary. Describe findings in summary form.
7. Update files with follow-up data, error corrections, etc. as directed by the COR.

8. Prepare data sets for transfer to personal computers, as specified by the COR.
9. As at the direction of the COR, respond to priority requests and changes of resource allocations rapidly, by appropriate activities and use of personnel.

I. Study Monitoring, Quality Control, and Reporting

1. Document each step in a specific study and maintain, in an orderly arrangement, all relevant material so that any aspect of a study may be reviewed and evaluated by the NCI staff at any point in time. Involved are the following:
 - a. Type letters and prepare forms and other documents necessary in the conduct of a study.
 - b. Duplicate study documents when the original sources cannot be retained.
 - c. Maintain a filing system of all materials relevant to a particular study, cross-referenced in a manner so as to make all of the material easily accessible. These materials shall be maintained under security in accordance with requirements of the Privacy Act as it applies to Contractors. Data for family studies shall be maintained in accordance with requirements of a Certificate of Confidentiality.
 - d. Maintain a log of decisions made during each study that affect the design, conduct, or analysis. Each entry shall include a brief explanation and date of the problem, the decision made, and the name of the NCI staff member who authorized the change.
2. Develop and use internal record-keeping procedures for assessing the progress and status of data collection, preparation and entry. These record systems may be paper files or computer systems.
3. Monitor and document the performance and progress of any work done under subcontract in the performance of a study.
4. Develop quality control procedures for the handling of biologic specimens specific for the needs of each study.
5. Report verification rates, discrepancy rates, and error rates for data collection, preparation and keying following the schedule agreed upon with the COR. Any unusual problems shall be brought immediately to the attention of the COR.
6. Provide monthly, annual and final technical progress reports and monthly budget reports, as specified by the NCI COR and/or designated representative.

J. Family Medical Record Room and Database Maintenance

1. Store the medical records of more than 1000 families (more than 10,000 individuals). Maintain storage system that makes misfiled records apparent.
2. Provide physical access to patient medical records within thirty (30) minutes by the COR and designated medical personnel 24 hours a day, 7 days a week.
3. Restrict access to the family medical records to authorized personnel. Any transport/delivery of records outside of the record room must be via secured or locked container. Maintain a tracking log of records that leave the medical record room. Insure that all Contract personnel who have access to these records have been satisfactorily trained with regard to issues of data privacy and confidentiality. Systematically follow up records that have been checked out to ensure timely return to the record room.
4. Add new family data to the existing computerized database (FAIR/FAIRVIEW) of records from high-risk families. The Contractor shall establish procedures to ensure that data are entered into FAIR/FAIRVIEW in a timely and accurate manner.
5. Maintain medical records with content and order as directed by the COR. File reports and other documents in the medical records within one business day of receipt.
6. Maintain pathology slide and paraffin block collection and related databases.
7. Maintain clinical photograph database. These may consist of both paper prints and digital images.
8. Maintain photographic slides and prints in easily retrievable archival quality storage in the Medical Record Room.
9. Maintain referral/consult records as specified by the COR.

K. Transition - Out

Within 60 days of the contract expiration date, the Contractor shall submit a Transition – Out Plan that describes the process, details, and schedule for providing an orderly transition during the Contract’s Transition Term of 30 calendar days, in accordance with the guidance herein for all elements of the Statement of Work.

The objectives of the Transition Plan are: to minimize the impacts on continuity of operations; maintain communication with staff and affected communities; identify key issues; and overcome barriers to transition. The Contractor is responsible for performing due diligence to ensure that all the transition activities are identified, negotiated, and

completed during the Transition Term. The Contractor shall establish a transition management team capable of providing overall management and logistical support of all transition activities. The Contractor shall develop a resource-loaded project management schedule compatible with predecessor contractor software (if different). Milestones and measurable commitments will be included in the schedule. The Contractor will regularly report status to the NCI at periodic meetings and through regular written reports.