

Base Statement of Work
National Cancer Institute Surveillance Epidemiology and End Results

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform this Statement of Work.

Scope

The purpose of the National Cancer Institute (NCI) Surveillance Epidemiology and End Results (SEER) Program is to assemble and report annual estimates of cancer statistics that pertain to incidence, prevalence, and patient survival; monitor trends to identify important changes in cancer rates for population subgroups defined by geographic, demographic, and social characteristics; provide information on changes over time in stage of disease at diagnosis and types of therapy, as well as associated changes in cancer patient survival; carry out special studies that provide insight into trends in cancer rates, treatment patterns, and other relevant aspects of cancer control; and provide an infrastructure to support cancer research through its publicly available data.

The Contractor shall perform the following tasks. The specific requirements will be identified in each Task Order Statement of Work:

NOTE #1 TO OFFEORS: For an Offeror to be considered responsive, Offerors are (1) required to submit a technical proposal for Task Areas 1 – 9 of the Base Statement of Work; and (2) submit both technical and cost proposals in response to Sample Task Order A - Core Infrastructure Support Activities and Sample Task Order B - Virtual Pooled Registry.

TASK AREA 1 - CONTRACT KICKOFF MEETING

- a. The Contractor shall attend the Contract Kick-off Orientation conference call meeting with Contracting Officer's Representative (COR) and Contracting Officer (CO).

Task Area 2 – Administration Activities

The Contractor shall perform the following administrative activities, to include but not limited to the following:

1. Manage staff and resources to effectively provide services for multiple concurrent tasks orders.
2. Ensure quality assessment/quality control of the work performed, fostering internal/external communications, tracking activities, and monitoring the budgets of task orders.
3. Submit all data and documents to NCI or as designated by the COR.
4. Comply with approved Disaster Recovery Plan.
5. Comply with the approved Management of Sensitive Information Plan.
6. Comply with the approved Data Collection Plan.

7. Comply with the approved Data Sharing Plan.
8. Comply with the approved Configuration Management Plan.
9. Comply with System Review Analysis and Performance Metric Standards.
10. Comply with HHSAR 352.239-73(b) Electronic Information and Technology Accessibility Notice (December 2015).
11. For all reports, comply with Section 508 Standards at: <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards/section-508-standards>.
12. Comply with HHS-OCIO-2009-0002.001S Standard for Encryption Language in HHS Contracts at: <http://www.hhs.gov/ocio/policy/2009-0002.001s.html>.
13. Comply with requirements for Federal Information Security Management Act (FISMA) Moderate controls as set forward in FIPS 199 (<http://csrc.nist.gov/publications/fips/fips199/FIPS-PUB-199-final.pdf>), FIPS 200 (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>) and the most recent version of NIST SP 800-53 (<http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf>)
14. Comply with FAR 52.239-1 Privacy or Security Safeguards (August 1996)
15. As applicable to the Task Order, comply with HIPAA Security Rule as: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/nist80066.pdf>.
16. Comply with (HHSAR 352.237-75) Key Personnel (December 2015) and (HHSAR 352.224-70 Privacy Act (December 2015)).

TASK AREA 3 – CORE INFRASTRUCTURE SUPPORT ACTIVITIES

The CORE Infrastructure provides for the identification and reporting of the following. SEER Program reportability is subject to change at the direction of the COR.

All neoplasms diagnosed prior to the year 2001 with a behavior code of '2' or '3' in the International Classification of Diseases for Oncology, Second Edition (ICD-O-2) shall be reportable.

All neoplasms diagnosed in 2001 and later with a behavior code of '2' or '3' in the International Classification of Diseases for Oncology, Third Edition (ICD-O-3) shall be reportable.

The neoplasms in ICD-O-2 or ICD-O-3 shall be reportable for sites other than skin (C44.0-C44.9) including but not limited to vagina, clitoris, vulva, prepuce, penis and scrotum (sites C52.9, C51.0-C51.9, C60.0, C60.9, and C63.2).

If a '0' or '1' behavior code term in ICD-O-2 or ICD-O-3 is verified as in situ, '2', or malignant, '3', by a pathologist, these cases shall be reportable.

Tumors of the brain and central nervous system (C70.0-C72.9, C75.1-C75.3) with a behavior code of '0' or '1' beginning with January 1, 2004 diagnoses shall be reportable.

The following are exclusions based on histology and site:

- 8000-8005: Neoplasms, malignant, NOS of the skin (C44.0-C44.9)
- 8010-8046: Epithelial carcinomas of the skin (C44.0-C44.9)
- 8050-8084: Papillary and squamous cell carcinomas of the skin (C44.0-C44.9)
- 8090-8110: Basal cell carcinomas of the skin (C44.0-C44.9)

1. Perform Core Infrastructure Activities. This shall support the following activities.

a. Perform Casefinding Activities

The Contractor shall:

- 1) Identify and register all SEER Program reportable cancers diagnosed in residents of the Contractor's geographic coverage area based on the county of primary residence at the time of diagnosis. This shall require casefinding for all facilities where a cancer might be diagnosed including but not limited to hospitals, all pathology labs which provide cancer diagnostic services, all nursing homes identified as sources of cases through death clearance or pathology review, all free-standing medical facilities where cancer is diagnosed and treated, and the offices of physicians where significant numbers of otherwise unreported cases can be expected to be found.
- 2) Utilize electronic data capture systems such as electronic pathology (E-Path) reporting where available and participate in NCI efforts to increase e-Path coverage.
- 3) Establish agreements for electronic data transfer with all major case reporting facilities.
- 4) Ensure that they have legal access to the medical facilities and physician offices. This shall include initiating contact with the state legislature when applicable, for the purpose of obtaining the necessary statutory authority to gain access to such facilities or offices for cancer registration purposes.

b. Perform Data Acquisition

The Contractor Shall:

- 1) Ensure that all required data collected directly by the Contractor or submitted by other sources is within the Contractor's geographic coverage area.
- 2) Abstract each SEER Program reportable case or ensure that SEER Program reportable cases are abstracted by submitting sources in sufficient detail so that each cancer can be classified and coded in accordance with the SEER Program Coding and Staging Manuals.
- 3) When case data are submitted by other sources, such as hospital-based cancer registries, ensure that the submitted records are tracked and monitored in a manner, which ensures their completeness, timeliness and accuracy. Issues shall be addressed with submitting sources.

- 4) Ensure that there are follow-back procedures in place. Follow-back activities shall be done as part of other specific functions, including case finding, editing (visual), case consolidation, and/or follow-up and generally involve ongoing and iterative updating process. Follow-back activities include but are not limited to:
 - a) Follow-back activities to reporting facilities, hospital registry staff, physicians or other medical staff, and/or Registry staff intended to clarify missing or conflicting data initially gathered.
 - b) Maintaining the physician databases.
 - c) Follow-back to out-of-state or out-of-geographic coverage area, cases to obtain missing data for residents diagnosed and/or treated by out of area facilities.
 - d) Follow-back on unknown, missing, and/or inconsistent data.
 - 5) Ensure that all cases are edited and that case consolidation is conducted. Editing and case consolidation includes, but is not limited to:
 - a) All activities associated with screening for reportability,
 - b) Screening for multiple primaries,
 - c) Applying and interpreting coding rules,
 - d) Editing cases and reports (including reviewing and making corrections to individual cases failing computer edit-checks),
 - e) Making corrections to individual cases in order to reflect the receipt of new or up-to-date information,
 - f) Visually reviewing individual cases for completeness and correctness,
 - g) Providing feedback of current corrected/updated information back to reporting facilities,
 - h) All activities required to reconcile or compile data obtained from more than one source on the same person or tumor including determining sequence number (in the case of receipt of a new tumor),
 - i) Verifying that cases are unique individuals and data are associated with the correct person (including de-duplication activities),
 - j) Matching and merging patient, tumor, and admissions records (includes decisions/determinations regarding best value),
 - k) Resolving discrepancies, determining the best values, and distinguishing between complementary information and multiple primaries.
- c. Conduct Follow-up (Passive and Active) Activities.

The Contractor shall:

- 1) Obtain information on vital status for all active (alive at last follow-up) cancer cases that had a cancer diagnosed on or after January 1st of the first full year of data collection and were residents of the coverage area at the time of their diagnosis.
- 2) Have procedures in place to perform vital status follow-up for alive cases diagnosed prior to the last submission year (follow-up is not required for cases diagnosed in the last submission year) during the 22 month period before the November submission. These procedures shall consist of both active and passive methods.
- 3) For deceased cases, cause of death shall be obtained from the death certificate.
- 4) For cancer cases that were residents of the Contractors geographic coverage area at the time of their diagnosis and died outside of the Contractors geographic coverage area, every effort shall be made to obtain information on cause of death from the recording entity wherever the death certificate was filed.

d. Conduct Death Clearance Activities.

The Contractor shall have procedures in place for conducting death clearance. These procedures shall include, but are not limited to:

- 1) Obtaining and processing death records
- 2) Creating and updating Death Certificate Only (DCO) cases and information tracking forms
- 3) Following back to facilities and physicians for missed cases,
- 4) Interpreting DCO rules
- 5) Matching death records against hospital discharge files
- 6) De-duplication activities
- 7) Identification of second or later cases

2. Perform Data Submission

- a. The Contractor shall submit data to the National Cancer Institute (NCI) twice a year on each resident cancer case diagnosed from the first full year of data collection forward in the format specified by the COR. The primary submission shall be on November 1st of each year, which shall contain complete data for all patients diagnosed prior to January 1st of the preceding year (22 months prior to submission).
- b. In conjunction with this data submission, the Contractor, unless exempted by the COR, shall participate in the Indian Health Service (IHS) linkage to improve the classification of American Indian/Alaska Native cancer cases.
- c. The second data submission shall be submitted on the last day of February of each calendar year. This submission shall provide case data for patients diagnosed prior to January 1st of the preceding calendar year (14 months prior to submission).
- d. No information shall be submitted regarding patient identifiers (e.g., name or Social Security Number (SSN)) or the hospital where diagnosis and/or treatment occurred as a part of data submission.

3. Comply with Data Quality Requirements.

The Contractor shall meet the goals pertaining to data quality as measured by SEER*DMS statistical modeling. These include but are not limited to:

- a. The Contractor shall attempt to ensure completeness based on several SEER*DMS statistical models. The percentage of expected cases reported in the November submission shall be no less than 98 percent. The percentage of expected cases reported in the February submission shall be no less than 95 percent.
- b. Follow-up: For all cases with a primary invasive cancer (sequence number 0 or 1), the follow-up percentage shall be no less than 85 percent for cases diagnosed under the age of 20, no less than 90 percent for cases diagnosed between the age of 20 to 64, and no less than 95 percent for cases diagnosed at the age of 65 or older.
- c. One-year reporting delay: The one-year reporting delay shall be no greater than 2 percent for cases reported in the November submission. The one-year reporting delay shall be no greater than 5 percent for cases reported in the February submission.
- d. DCO Cases: The percentage of cancers diagnosed only by a death certificate shall be greater than 0 percent but shall be less than 1.5 percent.
- e. Missing Cause of death in Cases Known to be Dead: Shall be no greater than 2%.

- f. Unknown or ill-defined primary site: Excluding DCO cases, shall be no greater than 2%.
- g. Non-specific histology: Excluding DCO cases, shall be no greater than 2%.
- h. Unknown laterality: Excluding DCO cases, shall be no greater than 2%.
- i. Invalid or missing census tract: Shall be no greater than 1.5%.
- j. Urban Geocoding Accuracy: Excluding DCO cases, cases coded 1 or 2 for census tract certainty in county with > 75% of population in urban area shall be no less than 95%.
- k. Rural Geocoding Accuracy: Excluding DCO cases, cases coded 1 or 2 for census tract certainty in county with < 75% of population in urban area shall be no less than 85%.
- l. The Contractor shall meet additional goals as directed by the COR and shall comply with the new data quality goals within one calendar year.

4. Conduct Quality Control/Quality Improvement Activities

The Contractor shall conduct quality control /quality improvement activities at the Contractor's registry level and shall participate in project specific activities, including but not limited to:

a. Conduct Registry Quality Control/Quality Improvement Activities

The Contractor shall have approved plans and procedures for ensuring the quality of collected data and correcting any issues of problems encountered in the collection of data:

- 1) Developing an overall quality control/quality improvement plan for the Registry,
- 2) Incorporating the review of findings from various quality control audits into the quality improvement plan, education, and identification of training needs,
- 3) Responding to edit requests and telephone calls from abstractors,
- 4) Providing regular formal feedback or documentation of questions and answers to registrars to address abstracting, coding, histology, staging, and other issues,
- 5) Maintaining and updating data dictionaries, coding manuals, and procedure manuals,
- 6) Reviewing SEER and North American Association of Central Cancer Registries (NAACCR) edits and updating local edits as indicated,
- 7) Ensuring that abstracting vendors comply with State requirements,
- 8) Conducting inquiries to update facility, lab, and hospital information,
- 9) Developing and running region-specific or customized edits,
- 10) Reviewing SEER Inquiry System questions (SINQ) and posting these with responses and comments on the website,
- 11) Monitoring the timeliness and completeness of annual reporting utilizing both internal and external reports and assessments of reporting, timeliness, meeting established deadlines, follow-back responses, and other Registry operations,
- 12) Responding or replying to SEER inquiries related to inconsistencies in data,
- 13) Conducting quality assurance activities associated with cases prepared for case-sharing with other states,
- 14) Conducting various Region-only audits (Case-Finding audits, Re-abstracting audits, mini-reliability studies; recoding audits; and others as appropriate), including protocol development; audit administration; data analysis; reporting and recommendations, and corrective action plans,
- 15) Performing local individual abstractor/coder audits, cancer site audits, and ad hoc audits as needed,
- 16) Providing formal feedback to audited facilities or individuals.

b. Conduct Project-Specific Activities

The Contractor shall participate in NCI defined quality control/quality improvement (QI/QC) activities.

- 1) Leading or participating in National Cancer Institute (NCI) quality control studies,
- 2) Participating in development of new SEER coding rules, guidelines, and documentation,
- 3) Participating in SEER training activities including the annual SEER coding workshop,
- 4) Reviewing and testing new SEER coding software tools,
- 5) Attending SEER QC/QI meetings,
- 6) Providing expertise to the overall SEER quality control community

5. Conduct Education and Training Activities.

The Contractor shall conduct local level education and training activities to ensure the requirements of the Statement of Work are met. The Contractor shall also provide project-specific training as required. Training activities include but are not limited to:

a. Conduct Local Level Training

The Contractor shall have plans and procedures for ensuring that Contractor staff have the education and continued training needed to ensure the collection and processing of high quality data. These plans and procedures shall include a process for continual staff learning using SEER*Educate resources.

b. Conduct Project-Specific Training

The Contractor shall participate in the following NCI defined education and training activities.:

- 1) Developing or reviewing training modules.
- 2) Answering or reviewing questions for SINQ or Ask a SEER CTR.
- 3) Developing or reviewing manuals or manual chapters.
- 4) Conducting program, regional, or national level training.

6. Utilize Central Registry Data Management Software (SEER*DMS)

- a. The Contractor shall conduct all central registry data management related activities using SEER*DMS.
- b. Unless other provisions are provided and approved by the COR, in coordination with the NCI Information Systems Security Officer (ISSO), SEER*DMS shall be located at an NCI designated hosting facility employing FISMA Moderate level controls.
- c. The Contractor shall participate in the SEER*DMS Change Control Board (CCB) meetings or any successor to the CCB to discuss modifications and enhancements to SEER*DMS.

7. Comply with Data Security Requirements.

- a. The Contractor shall ensure that all desktops, laptops, tablets, smart phones, and other mobile devices that house Personally Identifiable Information (PII) are properly protected against the disclosure of this information through loss or theft.
 - b. The Contractor shall install computer virus detection software on all desktops laptops, tablets, smart phones, and other mobile devices used to access information on behalf of the federal government. Virus detection software and virus detection signatures shall be kept current. The Contractor shall install software/hardware patches and upgrades to protect automated federal information assets.
 - c. The Contractor shall ensure that there are sufficient physical security procedures in place to include:
 - 1) Providing controlled limited access to the physical area which houses the cancer registry,
 - 2) Limiting access to resources such as file rooms, printers, copy machines, and faxes to registry or contractor employees only,
 - 3) Ensuring that employees who telework do so from either their home or from a telework facility and that they utilize secure methods for transmitting personally identifiable information (PII),
 - 4) Developing and maintaining nondisclosure and confidentiality agreements along with a policy for who signs and at what interval,
 - 5) Providing employee training in confidentiality and data collection, processing, transfer, storage, and disposal.
 - d. The Contractor shall be responsible for reporting all incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT@mail.nih.gov) via email within one hour of discovering the incident and shall follow-up as directed by the NIH Incident Response Team.
8. Conduct Data Linkages.

The Contractor shall participate in various linkages specified below. These linkages shall require the submission of PII to a trusted third-party honest broker for the purposes of linkage. The Contractor shall coordinate with the COR to ensure that any needed agreements between the Contractor and the trusted third-party honest brokers are in place before the start of any linkage to ensure the integrity of these processes.

- a. Conduct linkages or participate in NCI coordinated linkages. Examples of Contractor specific linkages include State Vital Records, Motor Vehicles, and voter registration. Examples of NCI coordinated linkages include National Death Index (NDI), Centers for Medicare & Medicaid Services (CMS), and Social Security Administration (SSA). Data linkages shall include the resolution of record linkage discrepancies and the review and updating of records.
- b. Participate in linkages & feasibility investigations to include any successor or supplemental linkages involving data from CMS, Bureau of the Census, and other linkages as determined by the COR.

- c. Participate in SEER-National Longitudinal Mortality Study (SEER-NLMS) Linkages including any successor or supplemental linkages involving data from the Bureau of the Census.
- d. Participate in all additional linkages determined by the NCI to be relevant to the SEER program at the direction of the COR.
- e. Participate in linkage feasibility investigations.

9. Conduct Data Exchange Activities

The Contractor shall establish and maintain case-sharing agreements with other State or regional central cancer registries. This shall include but is not limited to:

- a. Building relationships with out-of-state reporting facilities.
- b. Communicating with other central cancer registries to ensure collaborative relationships.
- c. Monitoring data sharing agreements and their file delivery timetables.
- d. Negotiating with legal affairs to develop the actual case-sharing agreements.
- e. Preparing files for exchange.
- f. Processing files received from outside the state or the geographic coverage area.

10. Provide Reports and Data Requests

- a. The Contractor shall facilitate access to the data by the public, the media, and private, state, and federal organizations. This shall include:
 - 1) Making summary cancer statistics available through periodic reports with wide dissemination
 - 2) Responding to queries and ad hoc information requests
 - 3) Responding to technical surveys and questionnaires
 - 4) Cooperating with hospital registries to provide comparison data for annual reports
- b. The Contractor shall facilitate access to the data by researchers from within and outside of the Contractor's organization. Researcher support shall include:
 - 1) Providing consultation regarding the processes and procedures for the use of registry data
 - 2) Maintaining a collaborative relationship with local Institutional Review Boards (IRB),
 - 3) Assisting researchers in matters related to IRB approvals
 - 4) Reviewing proposals related to utilization of registry data/resources
 - 5) Creating data sets for researcher use
 - 6) Maintaining a database of IRB approvals

11. Perform Other Ancillary Data Collection Infrastructure Activities

- a. The Contractor shall attend various trainings or meetings of the SEER Program and other organizations in order to ensure that the Contractor's staff can implement new codes or procedures, and for the exchange of ideas regarding solutions to problems, which arise in tumor registry operations.
- b. The Contractor shall participate in NCI initiated activities on the development and assessment of future plans for the SEER program including short, medium, and long-term goals, objectives, and strategies.
- c. The Contractor shall participate in other ancillary data infrastructure activities as defined by Task Orders.

TASK AREA 4 - SEER*EDUCATE

1. The Contractor shall conduct activities necessary for the development, enhancement, and maintenance of the SEER*Educate system. This shall include but is not limited to:
 - a. Maintaining the existing SEER*Educate functionality,
 - b. Ensuring new SEER*Educate functionality is developed and released as needed,
 - c. Developing and maintaining user and management reports,
 - d. Maintaining existing training content, and
 - e. Creating and validating new training content.

TASK AREA 5 - SEER*DMS MIGRATION ACTIVITIES

NOTE #2 TO OFFERORS: The Contractor should anticipate that a scheduled SEER*DMS migration may require 12 to 18 months to complete.

1. The Contractor shall:
 - a. Comply with their COR-approved Migration Plan, and
 - b. Comply with the migration as scheduled by the NCI based on the availability of resources and shall commence within 30 days of notification by the COR.
2. Migration activities shall include but are not limited to:
 - a. Obtaining all required data use agreements and approvals for data transfer,
 - b. Participating in requirements analysis for the system infrastructure and technical design,
 - c. Providing detailed database documentation,
 - d. Providing periodic data files for use in migration,
 - e. Responding to questions related to data issues,
 - f. Participating in requirements analysis for the development of algorithms and configuration,
 - g. Participating in functional reviews,
 - h. Participating in beta testing, and
 - i. Participating in training.

TASK AREA 6 – PATTERNS OF CARE/QUALITY OF CARE STUDIES

The Contractor shall conduct Patterns of Care/Quality of Care (POC/QOC) studies or any successor or supplement to the Patterns of Care Studies. Patterns of Care/Quality of Care (POC/QOC) studies describe, characterize, and compare practice patterns and treatments provided for cancer in different geographic areas of the United States. POC/QOC studies are conducted to satisfy a Congressional directive (under Public Law 100-607, Sec. 413 (a) (2) (C) adopted November 4, 1988) to the National Cancer Institute (NCI). The studies investigate; evaluate state-of-the-art cancer therapies for patients with specified cancer sites. They also evaluate the dissemination of these therapies into community practice, disseminate findings in scientific journals and professional meetings; and work with professional organizations to develop educational or training opportunities to improve the use of state-of-the-art cancer therapy in community practice. The Contractor shall have the capability or the ability to procure and/or provide services needed to conduct the studies. These activities may include but are not limited to:

1. Describing the use of adjuvant therapy and verifying it with the treating physician or with a unified record
2. Characterizing the practice patterns in different communities
3. Describing more completely the use of surgery as treatment
4. Comparing the patterns of treatment (surgery, radiation therapy, chemotherapy immunotherapy, hormonal therapy) over time and by age, sex, race/ethnicity, and insurance status
5. Describing comorbidities and the effect of co-morbid conditions on treatment
6. Describing treatment by hospital characteristics (i.e., profit vs. not for profit, teaching vs. non-teaching, bed size, etc.)
7. Describing the use of diagnostic tests and compare their use by demographic variables and geographic region
8. Describing the use of biomarkers
9. Matching the patterns of care data with the SEER-Medicare linked files as appropriate by age
10. Comparing the outcomes in community practice to the outcomes obtained in clinical trials.
11. Complete a designated number of abstracts as indicated in each Task Order Statement of Work
12. Verify, by physician contact or by abstracting a unified medical record the therapy given to each patient: radiation, chemotherapy, immunotherapy, and hormonal therapy and other therapies used in the treatment of their selected cancers. In conducting studies requiring physician contact, the Contractor shall coordinate with the COR to either obtain a clinical exemption from the National Institutions of Health (NIH) or obtain clearance for the questionnaire from the Office of Management and Budget, prior to initiation of the study
13. Conduct quality control activities by re-abstracting a percentage of randomly sampled cases
14. Abstract data onto data collection forms and enter the data into the abstracting software provided by the NCI or abstract directly into the abstracting software with the appropriate consolidation of data from multiple sources
15. Appropriately sample new cases registered after the initial sample was drawn.
16. Track study progress, noting successes and failures
17. Obtain local Institutional Review Board (IRB) approval as appropriate for the Contractor's Institution

TASK AREA 7 – ANCILLARY STUDIES AND ADDITIONAL PROJECTS

1. The Contractor shall perform the following tasks that include but are not limited to:
 - a. Obtain IRB approval as required.
 - b. Conducting slide reviews.
 - c. Re-abstracting medical records.
 - d. Providing rapid case ascertainment in support of studies or clinical trial enrollment.
 - e. Obtaining additional follow-up data that would include information on selected patient and disease characteristics.
 - f. Linking the registry database with other databases for the purposes of obtaining information relevant to the study of cancer.
 - g. Collecting additional data items for the purposes of obtaining information relevant to the study of cancer.
 - h. Conducting studies of various aspects of registry operations.
 - i. Development of statistical methodologies that provide for the analysis of cancer registry data or that pertain to general cancer surveillance issues.
 - j. Development of mathematical models that relate to cancer control issues.
 - k. Conducting studies, which involve patient interviews or surveys to collect information on knowledge, attitudes, outcomes, and practices, related to any aspect of cancer control.
 - l. If a project or study involves patient interviews or surveys the following shall be required:
 - 1) If a survey instrument is utilized it shall require Office of Management and Budget (OMB) approval, prior to initiation of the study
 - 2) If biologic material is collected it shall be maintained by the Contractor
 - 3) In conducting studies requiring interviews of cancer cases, the Contractor shall coordinate with the COR to either obtain a clinical exemption from the National Institutes of Health (NIH) or obtain clearance for the questionnaire from the Office of Management and Budget, prior to initiation of the study
 - 4) All provisions of the Health Insurance Portability and Accountability Act shall be complied with in the conduct of these studies

TASK AREA 8 - VIRTUAL TISSUE REPOSITORY

Experience and best practices (<http://biospecimens.cancer.gov/practices/>) of NCI indicate that the NCI Surveillance, Epidemiology and End Results (SEER) Program can support biospecimen research using a SEER-linked Virtual Tissue Repository (VTR). A SEER VTR, with its population representativeness and large sampling frame is a unique resource for assembling robust collections of biospecimens, even for rare tumors and outcomes. SEER annotation includes demographic and clinical characteristics such as tumor histology, biomarker status, treatment and outcome. Annotation can be augmented with custom data, including detailed chemotherapy, time to recurrence, and body mass index. The Contractor shall have the capability or the ability to procure and/or provide services needed to do the following.

1. Participate in the Virtual Tissue Repository or any successor or supplement to the Virtual Tissue Repository. Activities shall include but are not limited to:
 - a. Determining biospecimen availability.
 - b. Identifying and retrieving biospecimens.
 - c. Performing custom annotation.
 - d. Performing pathology review of biospecimens.

- e. Assisting with study IRB clearance.

TASK AREA 9 - VIRTUAL POOLED REGISTRY

The purpose of the Virtual Pooled Registry (VPR) is to create a capacity similar to the National Death Index without the creation of an aggregated national level cancer patient database. The VPR will consist of "one stop shop" process through which an interested researcher could submit one research application and one research file which will undergo one standardized linkage simultaneously at multiple registries.

1. The Contractor shall participate in the Virtual Pooled Registry or any successor or supplement to the Virtual Pooled Registry.
2. The Contractor shall coordinate with the COR to ensure any needed agreements between the Contractor and the trusted third-party honest brokers are in place to ensure the integrity of these processes.
3. Virtual Pooled Registry activities shall include but are not limited to:
 - a. Installing the NCI provided Virtual Pooled Registry linkage software.
 - b. Resolution of record linkage discrepancies.
 - c. Assisting investigators with IRB submissions to obtain requested information.
 - d. Participate in a central IRB process.

Attachment 21

Mandatory Qualification Criteria

Listed below are the mandatory qualification criteria. **THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL.**

The **MANDATORY QUALIFICATION CRITERIA** establishes conditions that must be met at the time of receipt of the original proposal by the Contracting Officer in order for a proposal to be evaluated by the Peer Review Panel.

1. The Offeror shall document that their registry is the designated agent to collect data on cancer patients for the specified geographic area. If an Offeror is named in the legislation authorizing collection of cancer data, a copy of the statutory requirement authorizing collection of cancer data by the Offeror is required at proposal submission. If the Offeror is not named in the legislation authorizing collection of cancer data, a letter documenting that the Offeror has received a delegation of authority to collect data as well as a copy of the statutory requirement authorizing collection of cancer data by the designee is required at proposal submission.
2. The Offeror shall document through an attesting letter signed by both the proposed Principal Investigator and Business Official that:
 - a. The Offeror's coverage area includes only geographic areas within the United States of America. Geographic area refers to a state, tribal area, territory, or federal district, combinations of states, tribal areas, territories, or federal districts, or combinations of counties or parishes. Combinations of counties or parishes may cross state, tribal area, territory, or federal district boundaries.
 - b. The Offeror's laws and policies allow for the worldwide release of cancer surveillance data to researchers and other investigators.
 - c. The Offeror is currently deployed on and committed to the continued use of SEER*DMS or the Offeror is committed to migrating to and using SEER*DMS within a designated time period to be determined by the NCI.