Attachment 1

DRAFT STATEMENT OF WORK

CONTRACT TITLE: Health effects in Chernobyl Cleanup Workers in Ukraine

Background

Following the Chernobyl Nuclear Power Plant accident on April 26, 1986, approximately 150,000 cleanup workers (primarily men) living in Ukraine participated in various recovery activities. Since the accident, these individuals were invited for clinical examinations every two (2) years at the National Research Center for Radiation Medicine, Hematology and Oncology (NRCRMHO), Association for Radiation Medicine and Radiation Safety in Kiev, Ukraine. Although a population of Ukrainian cleanup workers has been established for many years, there is no cancer cohort with reliable doses estimated for a range of organs. To resolve major questions about cancer mediators, precancer risks and other diseases following protractive exposure to ionizing radiation The Chernobyl Research Program (CRP) at Radiation Epidemiology Branch (REB), Division of Cancer Epidemiology and Genetics (DCEG), National Cancer Institute (NCI) (CRP/REB/DCEG) and NRCRMHO are constructing the Cleanup Workers Clinical Cohort consisting of 10,965 individuals from which radiation doses may be estimated using a brief survey. Currently information (e.g., vital status, last known address, cancer registry data, and Chernobyl State Registry data) is confirmed through the mail survey for 1,639 from 10,965 individuals. This procurement is for the continuation of this activity. Follow-up of this cohort will occur through previously established biannual medical examinations at NRCRMHO and linkage to the National Cancer Registry of Ukraine (NCRU) and the State Chernobyl Registry (SCR).

I. Period of Performance

The estimated period of performance for this procurement is from July 1, 2027 through June 30, 2032 with a base period of 12 months and 4 option periods of 12 months.

II. Scope

The specific objective of this procurement is to maintain the Cleanup Workers Clinical Cohort by updating the demographic, clinical and epidemiologic data through a mail survey and passive follow-up through linkage to the NCRU and the SCR.

III. Description of Work

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work (SOW). The Contractor shall perform work defined more specifically here:

1. Update vital status and last known address through a mail survey for annual target of at least **2,000** subjects of the Cleanup Workers Clinical Cohort (name/ address/ telephone number/ email, close relative's name/ address/ telephone number/ email) as described in the approved study protocol and Operations Manual. Use tracing management systems to

maximize participation and reduce loss rates for all data collection efforts. Support and manage systems to describe document control for best name, date of birth, last known address, and last known vital status with appropriate dates. After the target number of 10,965 has been reached, the mail survey shall continue cyclically starting with the subjects that were surveyed prior to this contract.

2. Conduct linkage of the information of subjects to the NCRU and the SCR to ascertain cases of cancer and other diagnoses; to compare incidence rate among the study subjects with corresponding indicators for the entire Ukrainian population. Update the databases with information obtained as a result of record linkage to the SCR and NCRU, and ongoing data records cleaning procedures.
3. Deliver accurate, complete, and up-to-date electronic databases (Data Services or Information Retrieval Systems | Section508.gov), including cancer registry variables, as specified by NCI PIs. No personally identifiable information shall be sent (e.g., no names, birth year/month only).
4. Under the direction of NCI, implement procedures needed to assure the quality of data collected, entered, and managed. Provide written Manual for Quality Control Procedures used along with error or problem rates. Maintain comprehensive documentation for the study datasets.
5. Maintain electronic datasets (Data Services or Information Retrieval Systems | Section508.gov) with updated demographic information and User's Guide to Data Files. Deliver report summarizing results of demographic and contact information update. Deliver database with updated demographic information, only if requested by NCI. No personally identifiable information shall be sent (e.g., no names, birth year/month only).
6. Respond to data requests and questions concerning the Cleanup Workers Clinical Cohort and provide support to NCI investigators in their preparation of scientific presentations and papers.
7. Perform administrative, operational, and technical duties to support productive collaboration among the study personnel and NCI. This shall include participation in regular calls with NCI. In addition, this includes hosting a site visit and attending an in-person meeting of all stakeholders (schedules for calls and in-person meetings/site visits to be determined after award).

IV. Reporting Requirements/Deliverables

All reports required herein shall be submitted in electronic format. Security requirement is to abide by all Data Security and Data Privacy Laws and Practices in the Ukraine and to send deidentified data back to the U.S. upon request encrypted. No personally identifiable information (PII) shall be transferred to NCI in any of the task areas that include the transfer of data (e.g., no names, birth year/month only). All electronic reports shall be delivered as specified in the Deliveries Article of Section F of the contract.

All electronic reports submitted shall be conformant with Section 508 of the Rehabilitation Act of 1973. Additional information about formatting and testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: HHS Accessibility &

Section 508 | HHS.gov, under Accessibility Technical Resources | HHS.gov as well as Accessibility Conformance Checklists | HHS.gov. Additional guidance may be found at Create Accessible Digital Products | Section508.gov.

The Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or National Institutes of Health (NIH) Manuscript Submission reference number when citing publications that arise from its NIH funded research.

A. Scientific and Technical Reports:

1. Quarterly Progress Report

   The Contractor shall provide Quarterly Progress Reports that summarizes all contract activities. These reports shall be broken out for each task as outlined in the Statement of Work. Reports shall be tailored by task and include: 1) Summary of progress; 2) Summary of tasks that have been completed and the completion date; 3) Summary of tasks yet to be completed, whether or not these projects are on schedule, and discussion of any problems encountered in the collection, handling, or processing of data, including resolution of each problem; and 4) Suggestions for modification of the project plan.

   The reporting period for the Quarterly Progress Report is every quarter during the period of performance, which will commence upon award of contract. This report is due on or before the 15th calendar day following each reporting period.

2. Annual Progress Reports

   The Annual Progress Report shall include a summation of the results of the work done for the entire contract during the period covered. The period covered shall be twelve (12) months from the start date of the contract period of performance. This report is due on or before the 15th calendar day following each reporting period. A Quarterly Report shall not be submitted when an Annual Report is due.

3. Final Reports (Draft Final and Final)

   The Final Report shall include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to comprehensively describe the results achieved. Neither a Quarterly or Annual Report shall be submitted when a Final Report is due.

   The Contractor shall provide the CO and the COR with 1 copy of the Draft Final Report thirty (30) calendar days prior to the end of the contract period of performance. The COR will review the Draft Final Report and provide the Contractor with comments within 14 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary, and the final version delivered on or before the last day of the period of performance of the contract.

B. Other Reports/Deliverables

1. Data Files

   The data collected shall be edited and corrected (suitable for analysis) and sent

electronically with appropriate technical documentation (#2 below) in an encrypted format to NCI. Data files shall include the study databases with information in format as requested by the NCI. No personally identifiable information shall be sent to NCI (e.g., no first and last names, birth year/month only).

2. Technical Documentation

   Along with the Data Files, the Contractor shall submit to the Contracting Officer's Representative (COR) the Operations Manual for epidemiological aspects of the studies, User's Guide to Data Files, and Manual for Quality Control Procedures.

3. Section 508 Checklist

   The Contractor shall submit a Section 508 Checklist with each deliverable. The contract holder shall complete and submit applicable Section 508/Accessibility Conformance Checklists from the US Health and Human Services (HHS)'s HHS Accessibility & Section 508. These checklists aid in the creation and testing of digital contents as well as serving as verification or conformance reports.[1]

   These HHS Accessibility Conformance Checklists shall be submitted for all reports, files, or other digital contents submitted as part of this contract. Note that one representative Section 508 checklist-as-Conformance Report per file type shall suffice – that is, one Microsoft Word checklist shall represent all Word files submitted under this contact, one Microsoft Excel checklist shall represent all Excel files, one Adobe PDF checklist shall represent all PDF files, etc. Such representative Checklists shall be submitted each reporting period.

   - Web Sites, Web Applications & Software
   - Microsoft Word
   - Microsoft PowerPoint
   - Microsoft Excel
   - Adobe PDF

   Comparable, additional guidance and checklists may be found at Create Accessible Digital Products | Section508.gov

   - Create Accessible Documents | Section508.gov
   - Create Accessible Presentations | Section508.gov
   - Create Accessible Spreadsheets | Section508.gov
   - Create Accessible PDFs | Section508.gov

[1] These Checklists are in lieu of one Annual Report, which typically requires the use of an Information Technology Industry Council-provided Voluntary Project Accessibility Template ("VPAT"), the current version being VPAT 2.4Rev 508 (March 2022)