STATEMENT OF WORK

1. Introduction/Background.

The purpose of the DES Exposed Cohorts Follow-up Study, as required by congressional mandate under the DES Research and Education legislation, is to continue to monitor individuals participating in studies of DES for cancer risk, particularly among daughters as they approach menopause and among DES-exposed sons; assess the impact of and the risks associated with exposure to other hormones such as hormone replacement therapy in DES-exposed mothers and daughters; and study whether DES-exposed women and men will develop non-reproductive conditions.

2. References:

☐ This acquisition includes reference materials

☒ This acquisition does not include reference materials.

3. Scope and Tasks: The contractor shall supply all labor, materials, facilities, equipment, and supplies to perform the following tasks:

- Monitor the cancer incidence among the DES exposed daughters, sons and granddaughters compared with external and internal rates, with particular focus on cancers of the breast, uterus, ovary, prostate and colon and rectum.

- Monitor the mortality of mothers, daughters and sons.

- Monitor the incidence of validated diagnoses of cardiovascular disease, and reported diagnoses of diabetes, osteoporosis, fractures, hypertension and high cholesterol comparing DES exposed with unexposed sons and daughters.

- Monitor the incidence of preneoplastic events (in particular, CIN2+) and the incidence of benign lesions of the breast and urogenital tract among the exposed and unexposed daughters and granddaughters.

- Continue to evaluate differences in reproductive experience among the granddaughters.

- Compare mammographic densities between DES exposed and unexposed daughters.

a) Liaison

1) Establish contact with each of the four field centers selected by NCI.

2) Establish contact and coordinate activities as needed with NCI's computer programming support services contractor.

3) Assist in arranging communications or meetings, as needed, between the NCI Contracting Officer Representative and field center staff.

4) Attend and report on such meetings, provide background materials as needed and take action on recommendations in consultation with the NCI Contracting Officer Representative.

5) Respond to queries from NCI Contracting Officer Representative. Meet in-person with NCI Contracting Officer Representative at least quarterly.

b) Development of Study Materials and Manuals

1) Develop mail questionnaires to be sent to selected subpopulations as needed, in collaboration with the NCI Contracting Officer Representative and field center staff.

2) Develop and update procedure manuals for the study, in collaboration with the NCI Contracting Officer Representative and field center staff. Work with field centers and NCI Contracting Officer Representative to establish standardized procedures for each of the sub-studies.

3) Assist field centers in developing newsletters to be sent to cohort members.

4) Organize logistical aspects of pathology slide review for diagnoses of high grade cervical intraepithelial neoplasia, by receiving slides from field centers, and developing a tracking system for sending and receiving the slides to and from the designated central pathologist. The coordinating center will provide storage for the pathology slides returned from the pathologist or will return the slides to the field center in the case that the hospital has requested them back. The coordinating center is not responsible for the pathologist=s slide review costs.

5) Maintain and update the study web site (http://www.desfollowupstudy.org/).

6) Assist in organization of materials for package submitted to NCI Institutional Review Board.

c) Data Preparation and Processing

1) Receive mail questionnaires and abstract forms from field centers for data entry.

2) Coordinate and conduct National Death Index searches to determine vital status. Assist in reconciliation of vital status using available sources. Coordinate and conduct state cancer registries searches.

3) Coordinate State Cancer Registry searches to ascertain cancer status.

4) Scan mailed questionnaires. Enter data from questionnaires and abstract forms as needed.

5) Edit and correct computer files as needed.

6) Maintain a master study file with vital status and response to 1994, 1997, 2001, 2006, 2011 and next follow-up questionnaires and respond to requests by NCI Contracting Officer Representative.

7) Transmit computerized data files containing edited, corrected data to the NCI Contracting Officer Representative or representative at the completion of each wave of follow-up, or as appropriate.

8) Assist the study centers in *ad hoc* investigations that arise from the standard data collection.

d) Monitoring, Information Management, Reporting and Documentation

1) Utilize a computerized information system to monitor the progress of data collection.

2) Initiate regular monthly telephone calls to the field centers to monitor progress and address problems during the data collection phase of the study.

3) During the data collection phase of the study, receive monthly reports from the field centers and provide them to the NCI Contracting Officer Representative for review. On a quarterly basis, create a combined report from all the field centers to monitor the overall progress of the study.

4) Document all of the individual steps in the study and maintain orderly files of all relevant materials, so that any aspect of the study can be reviewed and evaluated by NCI staff at any time during the course of the study.

Included are the following:

i. Type letters, forms and other documents necessary to conduct the study.

ii. Maintain a filing system of all relevant materials, cross-referenced to permit easy access. These materials shall be stored in accordance with requirements of the Privacy Act.

iii. Maintain a log of all decisions made during the study that pertain to study design, conduct, and analysis. Examples of such decisions are criteria for selecting individual cohort members for participation in sub-studies, and coding decisions for questionnaires and medical records.