CEDCD Cancer Epidemiology Descriptive Cohort Database

Data Collection Form
5/16/2017

Thank you for taking the time to complete this form. The information you provide will populate the Cancer Epidemiology Descriptive Cohort Database (http://CEDCD.nci.nih.gov). Users of the CEDCD can access information about Cancer Epidemiology Cohorts, compare cohort characteristics, types of data collected, and tabulate counts of participants, cancer endpoints, and biospecimens. We hope you will find the CEDCD useful in identifying potential collaborators and facilitating future studies.

This form contains pre-filled information (wherever possible) from past entries. Please review for accuracy and update information as needed. The information on this form will be automatically uploaded to the CEDCD database (i.e., no duplicate data entry). Annual updates are planned to ensure that the database reflects accurate up-to-date information about your cohort.

Please return the completed form to Westat (cedcdhelpdesk@westat.com). If you have questions, please contact the CEDCD Helpdesk or Dr. Joanne Elena (elenajw@mail.nih.gov) directly.

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A. Basic Cohort Information *(If your cohort is comprised of more than one distinct enrollment period or population, please complete separate CEDCD Data Collection Forms to treat them as separate cohorts.)*

A.1a Cohort Name:	Carotene and Retinol Efficacy Trial
A.1b Cohort Abbreviation:	CARET
A.1c Cohort Website: (if available)	http://www.compass.fhcrc.org/caretWeb/Default.aspx
A.2 Date Form Completed:	_____ MM / DD / YYYY

A.3a Person who completed the form:

Name:	Gary Goodman
Position with the cohort:	Joint Member
Phone:	206-386-2122
Email:	gary.goodman@swedish.org

A.3b Contact Person for clarification of this form:

Is this the person to contact with questions about this form? ☐ No ☐ Yes

If no, please provide the name and contact information for correct person in the space below.

Name:	
Position with the cohort:	
Phone:	
Email:	

A.4 Cohort Principal Investigator(s):

Name:	Marian Neuhouser	Name:	
Institution:	Fred Hutchinson Cancer Research Center	Institution:	
Email:	mneuhous@fredhutch.org	Email:	
Name:	Mark Thornquist	Name:	
Institution:	Fred Hutchinson Cancer Research Center	Institution:	
Email:	mthornqu@fredhutch.org	Email:	
Name:		Name:	
Institution:		Institution:	
Email:		Email:	

A. Basic Cohort Information (continued)

A.5 If an investigator is interested in collaborating with your cohort on a new project, whom should they contact?

Name:	Becky Harbine ☐ Same as A.3a
Position with the cohort:	Project Coordinator
Phone:	206-667-5964 ☐ Same as A.3b
Email:	caret@fredhutch.org

A.6 What is the procedure for requesting data?

- ☐ Website, please specify: _____
- ☐ Policy attached (PDF)
- ☐ We do not have one

A.7 Cohort Description:

Please provide a short paragraph describing your cohort. This will be used as an overall narrative description of your cohort on the CEDCD website. You may provide a link to a description on your cohort's website.

The Carotene and Retinol Efficacy Trial (CARET) was a randomized, double-blind, placebo-controlled trial of the cancer prevention efficacy and safety of a daily combination of 30 milligrams (mg) of beta-carotene and 25,000 IU of retinyl palmitate in 18,314 persons who were at high risk for lung cancer. The investigators studied two high-risk populations: 4,060 men with extensive occupational exposure to asbestos, and 7,965 men and 6,289 women with at least 20 pack-years of cigarette smoking history. The trial began recruitment in 1985 and was halted in January 1996, 21 months ahead of schedule, with the twin conclusions of no benefit and substantial evidence of a harmful effect of the intervention on both lung cancer incidence and total mortality. Participants were followed for over nine years post-intervention, with updated lung cancer incidence and cardiovascular disease mortality findings published in 2004. On June 30, 2005, CARET stopped active follow-up of participants. During the active intervention phase of CARET, serum, plasma, whole blood, and lung tissue specimens were collected. These biospecimens make up the CARET Biorepository.

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A. Basic Cohort Information (continued)	
A.8 Eligibility Criteria:	Eligible Gender: ☑ Both genders ☐ Males only ☐ Females only Disease State: ☐ Cancer survivors only, specify cancer site:_____ ☐ Generally healthy, no previous cancer diagnosis ☐ Other, please specify:_____
A.9 Enrollment Information:	Total number of subjects enrolled: 18314 1985 (Year Started (YYYY)) to 1994 (Year Ended (YYYY)) Is enrollment ongoing? ☑ No ☐ Yes If still enrolling, please specify the target number you plan to enroll: _____ If still enrolling, please specify by when you plan to complete enrollment: _____ YYYY Age range of enrolled subjects: 45 To 74 Median age: 57 Mean age: _____
A.10 Specify time intervals when your questionnaire data were collected. For example, yearly, biannually, 2011-2013.	Specify: 6x/year during pilot phase (1985-1988), 3-4x/year during full-scale trial (1985-1996) and annually during post-intervention phase (1997-2005)
A.11 Most recent year when questionnaire data were collected:	2005 (Year (YYYY))
A.12 How was information from the questionnaire administered/collected?	In person ☐ No ☑ Yes Phone ☐ No ☐ Yes Paper ☐ No ☑ Yes Electronic / Web-based ☑ No ☐ Yes Other: ☐ No ☑ Yes, specify: Phone contacts and mailed questionnaires
A.13 Were any tools aside from questionnaires used for exposure data collection? (e.g., an accelerometer for recording physical activity)	☐ No ☑ Yes If yes, specify the instruments: Chest X-rays and spirometry (asbestos-exposed population only)

A. Basic Cohort Information (continued)

A.14 Does your cohort have any known restrictions on participating in collaborative projects involving pooling of data or specimens or use of specimens in genomic studies? (For example, restrictions due to the wording of the informed consent?)	☐ None ☐ Require Collaboration with Cohort Investigators ☐ Require IRB Approvals ☐ Require Data Use Agreements and/or Material Transfer Agreement ☐ Restrictions in the Consent Related to Genetic Use ☐ Restrictions in the Consent Related to Linking to Other databases ☐ Restriction on Commercial Use ☐ Other, please specify: _____ _____

B. Enrollment Counts (Record actual (not planned) recruitment counts)

B.1 Racial Categories	Ethnic Categories: Not Hispanic or Latino – Female	Not Hispanic or Latino – Male	Not Hispanic or Latino – Unknown/ Not Reported	Hispanic or Latino – Female	Hispanic or Latino – Male	Hispanic or Latino – Unknown/ Not Reported	Unknown/Not Reported Ethnicity – Female	Unknown/Not Reported Ethnicity – Male	Unknown/Not Reported Ethnicity – Unknown/ Not Reported	**Total**
American Indian/Alaska Native	64	85	0	0	0	0	0	0	0	149
Asian	59	148	0	0	0	0	0	0	0	207
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	75	455	0	0	0	0	0	0	0	530
White	5989	11078	0	0	0	0	0	0	0	17067
More Than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	29	57	0	73	202	0	0	0	0	361
Total	6216	11823	0	73	202	0	0	0	0	18,314

C. Data on Major Content Domains		
Please specify whether you collected data within these major content domains. Baseline refers to data collected at or near enrollment into the cohort.		
Did you collect data on:	**Collected at baseline**	**Collected during follow-up**
C.1 Socio-economic Status (e.g., income)	☑ No ☐ Yes	☐ No ☑ Yes
C.2 Education Level	☐ No ☑ Yes	☑ No ☐ Yes
C.3 Marital Status	☐ No ☑ Yes	☐ No ☑ Yes
C.4 Language/Country of Origin	☐ No ☐ Yes	☐ No ☐ Yes
C.5 Employment Status	☐ No ☐ Yes	☐ No ☐ Yes
C.6 Health Insurance Status	☐ No ☐ Yes	☐ No ☐ Yes
C.7 Anthropometry (e.g., weight, height, waist circumference)	☐ No ☑ Yes	☐ No ☑ Yes
C.8 Dietary Intake	☐ No ☑ Yes	☐ No ☑ Yes
C.9 Dietary Supplement Use	☐ No ☑ Yes	☐ No ☑ Yes
C.10 Complementary and Alternative Medicine	☐ No ☐ Yes	☐ No ☐ Yes
C.11 Prescription Medication Use (not related to cancer treatment)	☑ No ☐ Yes	☑ No ☐ Yes
C.12 Non-prescription Medication Use (not related to cancer treatment)	☑ No ☐ Yes	☑ No ☐ Yes
C.13 Alcohol Consumption	☐ No ☑ Yes	☐ No ☑ Yes
C.14 Cigarette Smoking	☐ No ☑ Yes	☐ No ☑ Yes

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C. Data on Major Content Domains (continued)		
Did you collect data on:	**Collected at baseline**	**Collected during follow-up**
C.15 Use of Tobacco Products Other than Cigarettes	Cigars ☐ No ☑ Yes Pipes ☐ No ☑ Yes Chewing tobacco ☑ No ☐ Yes E-Cigarettes ☐ No ☐ Yes Other ☑ No ☐ Yes, specify: _____ _____	Cigars ☐ No ☐ Yes Pipes ☐ No ☐ Yes Chewing tobacco ☐ No ☐ Yes E-Cigarettes ☐ No ☐ Yes Other ☐ No ☐ Yes, specify: _____ _____
C.16 Physical Activity	☑ No ☐ Yes	☑ No ☐ Yes
C.17 Sleep Habits	☐ No ☐ Yes	☐ No ☐ Yes
C.18 Reproductive History	☑ No ☐ Yes	☑ No ☐ Yes
C.19 Self-Reported Health	☐ No ☐ Yes	☐ No ☐ Yes
C.20 Quality of Life	☐ No ☐ Yes	☐ No ☐ Yes
C.21 Social Support	☐ No ☐ Yes	☐ No ☐ Yes
C.22 Cognitive Function	☐ No ☐ Yes	☐ No ☐ Yes
C.23 Depression	☐ No ☐ Yes	☐ No ☐ Yes
C.24 Other Psychosocial Variables	☐ No ☐ Yes	☐ No ☐ Yes
C.25 Fatigue	☐ No ☐ Yes	☐ No ☐ Yes
C.26 Family History of Cancer	☐ No ☑ Yes	☑ No ☐ Yes
C.27 Family History of Cancer with Pedigrees	☐ No ☑ Yes	☑ No ☐ Yes

C. Data on Major Content Domains (continued)

Did you collect data on:	Collected at baseline	Collected during follow-up
C.28 Environmental or Occupational Exposures (e.g. air contaminants/quality, occupational exposures and history, water source)	☐ No ☑ Yes	☑ No ☐ Yes
C.29 Residential Information (zip code, GIS)	☐ No ☐ Yes	☐ No ☐ Yes

C.31 Co-Morbid Conditions:

Did you collect data on:	Collected at baseline	Collected during follow-up
a. Diabetes	☐ No ☐ Yes	☐ No ☐ Yes
b. Stroke	☐ No ☐ Yes	☐ No ☐ Yes
c. COPD and/or Emphysema	☐ No ☐ Yes	☐ No ☐ Yes
d. Cardiovascular Disease	☐ No ☐ Yes	☐ No ☐ Yes
e. Osteoporosis	☐ No ☐ Yes	☐ No ☐ Yes
f. Mental Health	☐ No ☐ Yes	☐ No ☐ Yes
g. Cognitive Decline	☐ No ☐ Yes	☐ No ☐ Yes

C.32 Cancer Related Conditions:

Do you have information on the following cancer related conditions:

Acute treatment-related toxicity (e.g., diarrhea, nephrotoxicity) ☐ No ☐ Yes

Late effects of treatment (e.g., cardiotoxicity, lymphedema) ☐ No ☐ Yes

Symptoms management (e.g., fatigue, pain, sexual dysfunction) ☐ No ☐ Yes

Other ☐ No ☐ Yes, specify:

_____

_____

D. Cancer Information

D.1 Cancer Counts

Please enter the number of participants with these cancers by gender

			Gender	
ICD-9	**ICD-10/O**	**Cancer Type**	**Males**	**Females**
141-149	C00-C14	Oropharyngeal		
150	C15	Esophagus		
151	C16	Stomach		
152	C17	Small intestine		
153	C18	Colon		
154	C19-C21	Rectum and anus		
155	C22	Liver and intrahepatic bile ducts		
156	C23, C24	Gall bladder and extrahepatic bile duct		
157	C25	Pancreas		
162	C33, C34	Trachea, bronchus, and lung		
170	C40	Bone		
172	C43	Melanoma (excluding genital organs)		
174-175	C50	Breast		
180	C53	Cervix		
182	C54	Corpus, body of uterus		
183	C56	Ovary, fallopian tube, broad ligament		
185	C61	Prostate		
188	C67	Bladder		
189	C64-C66, C68	Kidney and other unspecified urinary organs including renal pelvis, ureter, urethra		
191	C71	Brain		
193	C73	Thyroid		
200-202	C81-85	Lymphoma (HL and NHL)		
203	C90	Myeloma		
204-208	C91-95	Leukemia		
		All Other Cancers		

D.2 Most recent year of confirmed cancer case ascertainment: 2005 (Year (YYYY))

D.3 How were your cancer cases ascertained?

- Self-report: ☐ No ☑ Yes
- Tumor registry: ☐ No ☑ Yes
- Medical record review: ☐ No ☑ Yes
- Other: ☑ No ☐ Yes, specify: _____

D. Cancer Information (continued)	
D.4 Did you collect information about cancer recurrence?	☐ No ☐ Yes
D.5 Do you have second primary cancer diagnosis?	☐ No ☑ Yes
D.6 Do you have cancer treatment data?	☑ No **(Go to D.6c)** ☐ Yes
D.6a Specify the treatment information you have:	Surgery ☐ No ☐ Yes Radiation ☐ No ☐ Yes Chemotherapy ☐ No ☐ Yes Hormonal therapy ☐ No ☐ Yes Bone marrow/stem cell transplant ☐ No ☐ Yes Other ☐ No ☐ Yes, specify: _____ _____
D.6b Specify the data sources the treatment information is from:	Administrative claims data ☐ No ☐ Yes Electronic record ☐ No ☐ Yes Chart abstraction ☐ No ☐ Yes Patient-reported questionnaire ☐ No ☐ Yes Other ☐ No ☐ Yes, specify: _____ _____
D.6c Would it be possible to collect treatment information from medical records or other sources?	☐ No ☐ Yes
D.7 Do you have cancer staging data?	☐ No ☑ Yes
D.8 Do you have tumor grade data?	☐ No ☑ Yes
D.9 Do you have tumor genetic markers data?	☑ No ☐ Yes If yes, please describe: _____ _____
D.10 Were cancer cases histologically confirmed?	Select only one: ☐ All ☑ Some ☐ None
D.11 Do you have cancer subtyping?	Histological ☐ No ☑ Yes Molecular ☑ No ☐ Yes

E. Mortality		
E.1 Most recent year of mortality follow-up:		2005 Year (YYYY)
E.2 How did your cohort confirm death?		U.S. National Death Index (NDI) linkage ☐ No ☑ Yes Death Certificates ☐ No ☑ Yes Other ☐ No ☑ Yes, specify Reported by spouse/personal contact (small number of cases report toward end of f/u)
E.3 Do you have date of death for most subjects?		☐ No ☑ Yes
E.4 Do you have cause of death for most subjects?	☐ No ☑ Yes	If yes, what type of death code was used? ICD-9 ☐ No ☑ Yes ICD-10 ☑ No ☐ Yes Not coded ☐ No ☐ Yes Other ☑ No ☐ Yes, specify
E.5 What is the number of deaths in your cohort as of most recent mortality follow-up?		4,712
F. Data Linkage and Harmonization		
F.1 Have you linked your cohort data to any other existing databases (e.g., Center for Medicare and Medicaid Services or NCI's Surveillance, Epidemiology and End Results (SEER) Program)?	☑ No ☐ Yes	If yes, specify:
F.2 Have you participated in projects that required cross-cohort data harmonization?	☐ No ☐ Yes	If part of a consortium, please specify:
F.3 Have you deposited data in an NIH sponsored data repository?	☐ No ☐ Yes	If yes, please select which repositories: CEDR ☐ No ☐ Yes dbGaP ☐ No ☐ Yes BioLINCC ☐ No ☐ Yes Other ☐ No ☐ Yes

G. Specimens Collected		
Specify the types of specimens you collected, whether the specimen was collected at baseline, and/or collected at other time points.		
Did you collect any of the following specimens:	**Collected at baseline**	**Collected at other time points**
G.1 Blood	☐ No ☑ Yes If collected, types of aliquots Serum ☐ No ☑ Yes Plasma ☐ No ☑ Yes Buffy Coat ☑ No ☐ Yes Other Blood Derivative ☑ No ☐ Yes	☐ No ☑ Yes If collected, types of aliquots Serum ☐ No ☑ Yes Plasma ☐ No ☑ Yes Buffy Coat ☑ No ☐ Yes Other Blood Derivative ☑ No ☐ Yes
G.2 Buccal/Saliva	☐ No ☐ Yes	☐ No ☐ Yes
G.3 Tissue (include tumor and/or normal)	☐ No ☐ Yes	☐ No ☐ Yes
G.4 If your cohort does not currently collect tumor blocks, do you have information on where the blocks are kept/stored?		☐ No ☐ Yes
Do you have:		
G.5 Genotyping Data (SNP)		☐ No ☑ Yes
G.6 Sequencing Data – Exome		☑ No ☐ Yes
G.7 Sequencing Data – Whole Genome		☐ No ☑ Yes
G.8 Epigenetic or Metabolic Markers		☑ No ☐ Yes
G.9 Other “omics” data		☐ No ☑ Yes

H. Technology Use	
H.1 In your cohort, have you adopted the use of mobile devices (i.e., tablet computers, personal digital assistants, etc.) for the collection and/or measurement of demographic or lifestyle factors, environmental exposures, and/or other types of information?	☐ Yes, please list or describe: _____ _____ _____ ☐ No, but we are currently considering it ☑ No, and we do not have any immediate plans to do so.
H.2 Have you adopted the use of cloud-based approaches for the collection, management, analysis, or distribution of any of your study data?	☐ Yes, please list or describe: _____ _____ _____ ☐ No, but we are currently considering it ☑ No, and we do not have any immediate plans to do so.

I. Additional Items for Inclusion on the CEDCD Website

As indicated on the CEDCD Approval Form, we are requesting the following items for inclusion on the CEDCD website. If you provided approval to post this information, please attach the documents and return them to Westat with this form. If they are already available on a publicly accessible website, please just provide the website address.

Document	Attached	Website URL (if document is not attached)
Questionnaires	☐	URL:
Main cohort protocol	☐	URL:
Data sharing policy	☐	URL:
Biospecimen sharing policy	☐	URL:
Publication (authorship) policy	☐	URL: