Components

- Definition of A component is a full consortium member of a CCOP. A consortium agreement (letter) between the CCOP organization and each component must be included in the application. OHRP assurance requirements must be met (see CCOP RFA, Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. CCOP Awardees Responsibilities <u>Federally Mandated Requirements</u>).
- Directions: Colum
- Column (2) Indicate if component is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.
 - (3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.
 - (5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.
 - (6) Indicate OHRP FWA number.

(1) Name of Component	Des	(2) scription	(3) ACOS Accredited	(4) Total Number d of Hospital	Numbe	5) r of New	(6) OHRP
Address Telephone Number	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)	Program Yes/No	(Hospital Only) 2008	Cancer Patients (In/Out patient) 2006 2007		Assurance Number

Affiliates

- Definition of Affiliate: Occasionally, a CCOP may want to establish a relationship with an organization that may be able to put a minimum number of patients on protocols but for which full consortium membership is not appropriate. OHRP assurance requirements must be met (see CCOP RFA Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. CCOP Awardees Responsibilities Federally Mandated Requirements).
- Directions: Column (2) Indicate if affiliate is a hospital, group/office practice, or other organization (indicate type). If hospital, indicate all applicable codes: 1=Not for Profit; 2=Federal Government (VA or MTF); 3=For Profit; 4=State/County/City Government; 5=Teaching 6=Medical School; 7=Approved Residency; 8=Formal Medical Affiliation with Student Rotation.
 - (3) Indicate if hospital has a current American College of Surgeons (ACOS) accredited cancer program.
 - (5) Use new cases diagnosed or receiving primary treatment at that hospital or physicians group, practice except for basal cell or squamous cell carcinoma of the skin.
 - (6) Indicate OHRP FWA number.

(1)	Des	(2) scription	(3) ACOS	(4) Total Number d of Hospital	(5) Number of New Cancer Patients (In/Out patient) 2006 2007		(6) OHRP
Name of Affiliate Address Telephone Number	H=Hospital G=Group O=Other	If Hospital enter applicable codes (see above)	Accredited Program Yes/No	of Hospital Beds (Hospital Only) 2008			Assurance Number

Column:

(1) Group by component/affiliate with which physician is affiliated. If a physician is affiliated with multiple components, list him/her only with primary component.

- (2) List all physicians who will participate in your CCOP, then indicate:
- (3) Type of practice: Group=G; Solo=S; or Hospital-Based =H.
- (4) Type of participation: enter "A" if the physician is expected to enter patients on NCIapproved clinical trials or "B" if the physician will be aware of trial requirements and actively support the CCOP but will not be actually registering patients (e.g., a pathologist or a diagnostic radiologist).
- (5 Physician's year of graduation from medical school.
- (6) Physician's specialty/subspecialty.
- (7) Indicate whether physician is board-certified or board-eligible for specialty.

(1) Component/ Affiliate	(2) Physician's Full Name	(3) Practice Type G/S/H	(4) Type A or B	(5) Grad. Year	(6) Specialty/ Subspecialty	(Bo Cert.	7) bard Eligible

Non-Physician Investigators Responsible for Entering Participants on Study

Directions:

- Column: (1) Group by component/affiliate with which individual is affiliated. If an individual is affiliated with multiple components, list him/her only with primary component.
 - (2) List all non-physician investigators responsible for patients/participants on cancer prevention and control trials in your CCOP.
 - (3) List highest degree attained.
 - (4) Enter the year the highest degree was confirmed.
 - (5) Individual's specialty/discipline.

(1)	(2)	(3)	(4)	(5)
Component/ Affiliate	Individual's Full Name	Highest Degree	Year Degree Confirmed	Specialty/ Discipline

All Other Personnel

Directions:

List all personnel (e.g., CCOP administrator/coordinator, clinical research associates, data managers, nurses) who will participate in the CCOP activities. Indicate CCOP component/affiliate with which person is most closely associated. Please complete all columns.

(1) Component/Affiliate	(2) Individual's Full Name	(3) Check if R.N.	(4) Highest Academic Degree	(5) Position	(6) Proposed Hrs/Week on CCOP Activities

Number of Newly Diagnosed Cancer Patients By Site

Directions:

Provide figures for the table below to the extent possible. Use new cases diagnosed or receiving treatment at that hospital, except for basal cell or squamous cell carcinoma of the skin. Submit a separate sheet for each hospital component.

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Name of Component:	
Information Source:	 Hospital Registry Regional Registry Population Based Registry Hospital Discharge Data Other

	Calendar \ 2006	Year 2007		Calend 2006	lar Year 2007
Breast Tumor			Non-Small Cell Lung		
Esophagus			Hodgkin=s Disease		
Stomach			Non-Hodgkin=s Disease		
Pancreas			Kaposi=s Sarcoma		
Hepatobiliary			Melanoma		
Colon			Head/Neck Tumors		
Rectum			Brain/Other CNS Tumors		
GI (other)			Endocrine		
Bladder			Osteogenic Sarcoma		
Kidney			Soft Tissue Sarcoma		
Prostate			Rhabdomyosaracoma		
Testis			Ewing=s Sarcoma		
GU (other)			Sarcoma (other)		
Cervix			Wilm=s Tumor		
Ovary			Neuroblastoma		
Uterus, Endometrial			Pediatric ALL		
GYN (other)			Pediatric AML		
Myeloma			Pediatric Acute Leukemia (other)		
Adult Acute Lymphocytic			Pediatric Lymphomas incl. Hodgkin=s Disease		
Adult Acute Non-Lymphocytic			Pediatric Solid Tumors/Others		
Chronic Leukemia			Other		
Small Cell Lung					

Total:

Accrual to NCI APPROVED Cancer Treatment Clinical Trials

Directions:

Column: (1)

(1) Indicate if currently participating in CCOP (Yes or No).

(3) Indicate trial source: name of cooperative group or cancer center.

 (4) Code the accrual by predominant practice mode for a given year: private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current entries and is not a substitution for the total treatment accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI-approved trials (e.g.: Cooperative Group/Cancer Center Research Bases).

(1) Names of Existing CCOP	(2) CCOP	(3)	(4) Number of Patients Entered			
Names of Existing CCOP Physicians* and Proposed Participating Physicians	Phys. (Y/N)	Trial Source	6/05-5/06	6/06-5/07	6/07-5/08	
Example: Jane R. Doe, MD	Y	NSABP	0/F	13/F	20/A	

Page Totals:

Existing CCOP Physicians:*

All Physicians:

Grand totals (last page only):

Existing CCOP Physicians

All Physicians:

* Applies to continuing applicant only

Accrual to ALL OTHER Cancer Treatment Clinical Trials

Directions: Column

(2) Indicate if currently participating in CCOP (Yes or No).

- (3) Indicate trial source: may be single institution studies, drug companies, local hospitals, or others.
- (4) Code accrual by predominant practice mode for given year: private practice = P; salaried academic = A; training/fellowship = F.

For all current and projected physicians, please list accrual by physician to all other trials (e.g.: pharmaceutical trials, etc.)

(1)	(2) (3)	(3)	(4) Number of Patients Entered					
Names of Existing CCOP Physicians* and Proposed Participating Physicians	CCOP Phys. (Y/N)	Trial Source	6/05-5/06	6/06-5/07	6/07-5/08			
Example: Jane R. Doe, MD	Y	Eli Lilly	0/F	5/F	10/A			

Page Totals:

Existing CCOP Physicians:* All Physicians:	 	
Grand totals (last page only):		
Existing CCOP Physicians	 	<u> </u>
All Physicians:	 	

Applies to continuing applicant only

Directions:

Column (2) Indicate if currently participating in CCOP (Yes or No).

- (3) Indicate trial source: name of cooperative group; cancer center; other organization
- (4) Code the accrual by predominant practice mode for a given year: private practice = P; salaried academic = A; training/fellowship = F.

This table is intended to reflect current and proposed entries and is not a substitution for the total cancer prevention/control accrual in the progress report (if applicable). For all current and projected physicians, please list accrual by physician to all NCI approved trials (e.g.: Cooperative Group/Cancer Center Research Base protocols).

(1) Names of Existing CCOP	(2) (3) CCOP	Numb	(4) er of Participants	Entered	
Physicians* and Proposed Participating Physicians	Phys. (Y/N)	Trial Source	6/05-5/06	6/06-5/07	6/07-5/08
Example: Jane R. Doe, MD	Y	NSABP	0/F	13/F	20/A

Page Totals:

Existing CCOP Physicians:*

All Physicians:

Grand totals (last page only):

Existing CCOP Physicians:

All Physicians:

* Applies to continuing applicant only

Accrual to NCI Approved Cancer Treatment Clinical Trials - (Summary for Progress Report)

Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.

Column (1) Indicate trial source: name of CCOP Research Base.

(2) Indicate the total number of patients and the credit equivalent (see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>) entered onto NCI approved cancer treatment clinical trials.

(1)	(2) Number of Patients - Credits									
ССОР	6/03 -	5/04	6/04 -	5/05	6/05 -	5/06	6/06 -	5/07	6/07 - 5/08	
Research Base	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits	Patients	Credits
Example: SWOG	63	63	75	75	60	55	80	80	75	70

Total Table 7A:

- Directions: Information to be provided as part of the Progress Report (for prior funding period of up to 5 years) for applicants submitting competing continuation applications.
- Column (1) Indicate trial source: name of CCOP Research Base.
 - (2) Indicate the total number of new entry credits & follow-up (FU) credits (see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>) for accrual to NCI approved cancer prevention/control clinical trials.

Special Instruction:

Please list the Study of Tamoxifen and Raloxifene (STAR) and the Selenium and Vitamin E Trial in Prostate Cancer Prevention (SELECT) on separate lines, if applicable.

(1)	(2) New Entry Credits & Follow-up Credits									
CCOP Research Base	6/03 - 5/04		6/04 - 5/05		6/05 - 5/06		6/06 - 5/07		6/07 - 5/08	
	New Entry Credits	FU Credits	New Entry Credits	FU Credits	New Entry Credits	FU Credit	New Entry Credits	FU Credits	New Entry Credits	FU Credits
Example: SWOG	20	0	10	0	25	0	10	0	15	1
Example: STAR (NSABP P-2)	20	0	30	6	30	15	25	24	0	31.5
Total Table 7B:										
Total Credits/Year (New & FU):										

Proposed Research Base Affiliation(s)

Directions: See CCOP RFA, Section VI. 2. A. Cooperative Agreement Terms and Conditions of Award, 2.A.1. Part A. CCOP Awardee Responsibilities, Affiliations of CCOP Awardees with Research Bases

Name & Location of Intermediary Institution, if Applicable	Treatment Research Yes/No	Cancer Prevention and Control Research Yes/No
	Institution,	Institution, Research

In the narrative, describe previous working relationships with proposed Research Base, if applicable. Include information on committee memberships and chairmanships as well as studies chaired. If one or more components participated as cooperative group affiliate program satellite hospitals, specify the years.

Limit to two pages.

Directions: Organize by Research Base(s). Use separate page(s) for each Research Base.

Name of Research Base: _____

This table should reflect the entire anticipated CCOP prevention and control accrual for the coming year.

(1)	(2)	(3)	(4) Anticipated Participants Accrual			
Title	NCI Protocol Number	Disease Site	Participants Available	Participants to be Placed on Study	Accrual Credits ¹	

Subtotal for Research Base:

Grand Total (last page only):

¹ For information on credit: see <u>http://prevention.cancer.gov/programs-resources/programs/ccop/credit</u>