Attachment: Formatting for Standard Cancer Center Summaries

Interim Revision
June 2006

Standard Cancer Center Information Summaries ensure consistency and thoroughness of peer review of competing applications and also are used to produce summary reports on the Cancer Centers Program.

Submit the following summaries by application type:

Code	Type of Application	Submit Summaries
Type 1 or 1A	New Competing or Amended	1, 2, 3, and 4
Type 2 or 2A	Competing Renewal or Amended	1, 2, 3, 4, and 5
Type 3	Administrative Extension with Funds	Consult Program Director
Type 5	Non-competing Continuation	1, 2, 3, and 4

Centers must also submit an electronic copy of their summary information, in a format compatible with the Cancer Centers Branch database, directly to the Cancer Centers Branch at the time the application is submitted. Send summary information as an attachment to the email address below:
ccsgdata@mail.nih.gov

General Instructions for Summaries:

- Insert the full grant number (e.g., 1P30CA000000-01) in the upper right corner of *each* page.
- Label summaries consistently (e.g., 1A, 1B, 1C).
- Provide *only* the information requested.
- Follow the example formats provided.

Summaries 1A, 1B, 1C, and 1D

Cancer Center Senior Leaders, Research Programs, Program Members, and Shared Resources as of the Reporting Date Indicated on the Summary

Summary 1A: List the names, titles, and academic degree(s) of the senior leadership of the Center (e.g., Cancer Center Director, Deputy Director, Associate Directors, etc.). Indicate a change in leadership with an asterisk next to the new leader's name.

Summary 1B: List the name of each Program, the name and academic degree(s) of the Program Leader, and the number of members in the program. Indicate a change in leadership by an asterisk next to the new leader's name. Assign a unique reference code (e.g., 01, 02, or GYN, GU, etc.) to each program in this table (for use in Summaries 2 and 4). Do not list developing programs. Use the code (ZY) for non-programmatically aligned members. Use this code also to identify projects (Summary 2) and trials (Summary 4) conducted by non-aligned center members. *Do not list individual program members*.

Summary 1C: Provide the total number of programmatically aligned and non-programmatically aligned members, and the total of all center members.

Summary 1D: List the full name of each shared resource of the cancer center, and the name and academic degree(s) of the resource director. Select up to three category codes for each shared resource from the list entitled "Categories of Shared Resources." Include *only* shared resources proposed for support by the CCSG. A listing of developmental cores supported with CCSG funds is optional, but useful for informational purposes. Developmental cores should be clearly identified as such if included.

Categories of Shared Resources: To each shared resource, assign the appropriate 3-digit numbers (maximum of three category codes) to indicate the applicable categories and subcategories.

Category 1: Laboratory Science	
1.01 Biochemical Analysis 1.02 General Animal Facility 1.03 Transgenic Facility 1.04 Special Breeding 1.05 Animal Health (Pathology/Histology) 1.06 Animal Health (QC) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.09 Nude Mouse 1.10 Specialized Animal Svcs (Irradiation) 1.11 Biohazard Control 1.12 Organic & Synthetic Chemistry 1.13 Chromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry	1.19 Cyclotron or Radiolabeling 1.20 Molecular Biology 1.21 Nucleotide Sequencing 1.22 Protein & Peptide Sequencing 1.23 Monoclonal Antibodies 1.24 NMR 1.26 MRI 1.27 Spectrometry, Other (Specify) 1.28 Radiobiology 1.29 Oligonucleotide Synthesis 1.30 Protein/Peptide Synthesis 1.31 Toxicology/Mutagenesis Testing 1.33 Confocal Microscopy 1.34 Xray Diffraction 1.35 DNA Array 1.36 Proteomics 1.37 Other (Define)
Category 2: Laboratory Support	
2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing	2.04 Illustration/Photography/Typeset 2.07 Tissue Culture 2.08 Media Preparation 2.10 Other (Define)
Category 3: Epidemiology, Cancer Control	
3.01 Cancer Control 3.03 Epidemiology 3.04 Survey	3.05 Nutrition 3.06 Other (Define)
Category 4: Clinical Research	
4.02 Clinical Trials Protocol Management & Data Management 4.03 Clinical – Other 4.04 Pharmacology (Animal)	4.05 Pharmacology (Lab Tests) 4.06 Human Tissue Acquisition & Pathology/Histology 4.07 Gene Therapy/Vector 4.08 Other (Define)
Category 5: Administrative	
5.01 Secretarial/Word Processing	
Category 6: Biostatistics	
6.01 Biostatistics	
Category 7: Informatics	
7.01 Clinical Research Informatics 7.02 Bioinformatics	7.03 Public Health/Epidemiology Informatics 7.04 Other (Define)
Category 8: Miscellaneous	
8.01 (Define)	

Outstanding University Cancer Center
Reporting Date: mm/dd/yyyy

Summary 1A - Senior Leadership

Name of Senior Leader	Title of Leader	Degree(s)
Sutton, Baylor D.	Principal Investigator	M.D., Ph.D.
Marucco, Gina L.	Deputy Director	Ph.D.
Galley, Mark E.	Assoc. Director for Basic Science	M.D.
Barrie, Thomas X.	Assoc. Director for Clinical Research	M.D., Ph.D.
Wong, Lee R.	Assoc. Director for Population Research	Ph.D.
Young, Jenni Jo	Assoc. Director for Administration	MHA

Summary 1B - Programs, Leaders, and Codes

Program Code*	Program Name	Program Leader(s)	Total # Members (including leader)
01	Molecular and Cellular Biology	Harrington, Marc, M.D, Ph.D.	25
02	Cancer Control and Prevention	Pham, Phuong T. K., Ph.D.	14
03	Epidemiology	Kaufman, Richard, M.D., Ph.D.	19
04	Developmental Therapeutics	Wood, Mary, M.D., Ph.D.	15
05	Women's Cancers	Miller, Barbara, Ph.D	22
CCGC	Cell Cycle and Growth Control	Neuhauser, Beverly N., M.D.	12
IM	Immunology	*Bhorjee, Jaswant, M.D., Ph.D.	27
ZY	Non-Aligned Members		12

* Centers may use any coding scheme they wish.

Summary 1C: Cancer Center Membership

Type of Member	Total Number
Programmatically Aligned Members (Individuals)	134
Non-Programmatically Aligned Members (Individuals)	12
Grand Total - Total Number of Center Members (Individuals)	146

Summary 1D: Shared Resources

Name of Shared Resource	Resource Director(s)	Category
Biostatistics	Francini, Benjamin, Ph.D.	6.01
DNA Microarray (developing)	Poole, Bruce D., M.D.	1.35
DNA Sequencing	Kelley, Steven, S., M.D., Ph.D.	1.22
Genomics and Proteomics	Goldstein, Phillip, M.D.	1.36
Bioinformatics	Mayrend, Jody, Ph.D.	7.02
Organic Synthesis	Singer, Richard, F., M.D., Ph.D.	1.12
Transgenic Animal Facility	Peterson, Douglas, M.D. / Barns, Nancy, M.D.	1.03, 1.06, 1.09

Summary 2A: Active Funded Projects as of the Reporting Date Indicated on the Summary

List all active funded, cancer-relevant projects competitively awarded by external sources to the fiscally responsible institution of which the cancer center is a part. If more than one institution is an integral part of the cancer center, provide a Summary 2A for each institution. Separate the list of grants in alphabetical order by Principal Investigator's last name into two parts:

- active funded research projects
- training and career development grants

In Summary 2A, do not sort or group grants by research Program or funding agency. (Note: A list of the externally funded projects by Program is requested for competing renewal applications as part of the programmatic description. See Section 8.0, Research Programs.)

For each project, list the Principal Investigator (PI); funding source (e.g., NCI, NIAID); complete project number with prefix and suffix showing the current grant year (e.g., 5R01 CA012345-06, 2N01CA654321-12); full project period (e.g., 3 yr:1/1/05-12/31/07 etc.) and the full project title.

Identify the CCSG approved research program(s) to which each project belongs in the "prog code" column using the codes from Summary 1B. For individual projects split among two or more research programs, list the grant in separate records for each program code to which the project is assignable, with the code in the "prog code" column, and the proportion attributable to the program in the "%" column. List once, in the first record only, the total direct costs of the grant in the "Direct Cost" column and the total costs (direct plus indirect) in the "Total Cost" column. For the last two columns, and for each record, calculate the proportional amounts of direct and total costs attributable to the program. The *Dubois, Y.* grant in the example format demonstrates how to document a split project. For national trials coordinated by your center, indicate only the direct and total costs for work performed at your center.

The sum of the percentages and dollars of any project assigned to different programs should not exceed 100%. However, if only part of a project is carried out within the cancer center, only the cancer center portion should be shown; the total percentage for such a project will be less than 100%.

Use the non-programmatically aligned code (ZY) to list any funded research projects or parts of projects not assigned to approved research Programs, and all other miscellaneous project assignments, such as instrumentation grants, cores of funded projects, a Cancer Information Service or SEER contract, and the CCSG itself.

For each project provide the direct and total costs (direct and indirect) for the current year. If an award consists of multiple projects (e.g., a P01 or SPORE), then list each assignable project with the name of the PI/name of the project leader as shown in the example format. P01 and SPORE administrative cores may be assigned to the non-programmatically aligned (ZY) category. See the example format for P01s.

Using the same procedure as above, list all training awards and research career development awards at the end of Summary 2A in a separate section, following a subtotal of the research grants. Identify all training grants with the program code "**T**," regardless of the source or type, including the F, K and T series NIH grants. Provide a subtotal of the training grants (if any) and a grand total of all grants.

Outstanding University Cancer Center
Active Funded Projects as of mm/dd/yyyy

RESEARCH PROJECTS

PI	Funding Agency	Grant #	Start Date	End Date	Proj Title	Dir Cost	Tot Cost	Prog Code	%	Prog Dir	Prog Tot
Alfred, L.	NIH	5R01DK059736-04	06/05/95	04/30/05	Regulation of mitochondrial inheritance in yeast	197713	342043	4	100	197713	342043
Blake, J.	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Program Director)	1116373	1931325				
Blake/Maleck	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Admin Core A)			ZY	100	235034	381460
Blake/Tillis	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Pharm Core C)			ZY	100	89579	146506
Blake/Guzic	NCI	5P01CA074846-07	07/23/01	04/30/06	Cancer Chemotherapy Program Project (Hem Onc Proj. 1)			2	100	280531	485088
Christy, W.	ACS	RPG-96-045-04-1	01/01/98	06/30/04	The role of an HNF-3 protein in c elegan foregut development	103537	128921	2	100	103537	128921
Dubois, Y.	NCI	5R01CA067893-02	09/08/97	06/30/03	Star trial (Tamoxifen vs. Raloxifene)	97784	165288	1	50	48892	82644
Dubois, Y.	NCI	5R01CA067893-02	09/08/97	06/30/03	Star trial (Tamoxifen vs. Raloxifene)			5	50	48892	82644
Gehr, A.	NCI	5N02C654321-09	04/01/01	05/31/06	Cancer Information Service	1421931	1766530	ZY			
Eutto, M.	NCI	5R01CA083747-03	12/27/02	11/30/03	Genetic epidemiology of breast cancer--BRCA1 and BRCA2	146128	252801	6	100	146128	252801
Royce, R.	NIH /Subcon-tract Univ.	5R01HL086850-04	08/01/02	06/30/04	Calpain and p120 catenin regulation of cadherin function	33333	55333	3	100	33333	53333
Sutton, B.	NCI	5P30CA011189-11	12/01/02	11/30/03	Core Grant	3439815	3760687	ZY			
			Research Subtotals:			6,556,614	8,402,928			1,183,639	1,955,440

TRAINING PROJECTS

PI	Funding Agency	Grant #	Start Date	End Date	Proj Title	Dir Cost	Tot Cost	Prog Code	%	Prog Dir	Prog Tot
Adams, Q.	Army	DAMD1702-1-11	09/01/02	08/31/04	Molecular study of bag domains: A new motif in prostate cancer	45368	48997	T	100	45368	48997
Burns, W.	NCI	5T32CA009579-01	05/01/87	02/28/04	Cell adhesion and effects on cell behavior	23470	25345	T	100	23470	25345
Carolan, R.	NIH	F32HL069595-02	07/01/01	06/30/05	Differentiation of a stem cell population in vivo	35585	35585	T	100	35585	35585
Dicenza, R.	NIH	K08MH001711-02	07/01/99	06/30/04	Serotonergic mechanisms is stress and anxiety	164882	178071	T	100	164882	178071
			Training Subtotals:			269,305	287,998			269,305	287,998
			Grand Totals:			6,825,919	8,690,926			1,452,944	2,243,438

Summary 2B: Active Funded Projects

List the total number of projects, the sum of direct costs and the sum of total costs (direct plus indirect) for each major funding agency category as follows: NCI, other NIH, ACS, NSF, other Peer Reviewed (*as defined by NCI in Part II, Eligibility Requirements, of the CCSG guidelines) and Non Peer Reviewed (Industry-sponsored and Other). The CCSG and training grants may also be included. Provide subtotals and a grand total where indicated.

Summary 2B – Active Funding (Example Format) 2P30CA654321-50

Outstanding University Cancer Center
Reporting Date: mm/dd/yyyy

Funding Agency	Total Number of Projects	Sum of Direct Costs	Sum of Total Costs (Dir+Indir)
NCI	20	5,579,706	9,085,388
Other NIH	47	9,446,080	14,851,293
ACS	2	80,000	80,000
NSF	5	666,030	1,087,092
Other Peer Reviewed*	9	6,420,432	6,967,926
Subtotal of Peer Reviewed	***83***	***22,192,248***	***32,071,699***
Industry Non Peer Reviewed	35	3,299,571	3,544,740
Other Non Peer Reviewed	30	4,013,038	5,472,172
Subtotal of Non Peer Reviewed	***65***	***7,312,609***	***9,016,912***
Grand Total (All Projects)	148	29,504,857	41,088,611

Summary 3: Reportable Patients/Participation in Therapeutic Protocols By Anatomic Cancer Site

Summary 3 documents which anatomic cancer sites are being treated at the cancer center and whether the center is placing these patients onto therapeutic protocols. Broadly, it summarizes the clinical research activities of the cancer center. (Note to Reviewers: Accrual data in Summary 3 and 4 do not correlate exactly and should not be directly compared.) For clarity and uniformity, use the following definitions:

Reporting Period: The 12-month period for which data are being provided (as defined by the Cancer Center).

Reportable Cancers: Malignancies with an International Classification of Diseases for Oncology -3 (ICD-O-3) behavior code of 2 or 3 should be reported, in accordance with the established requirements of registry standard setting organizations (see below).

Reportable Patients: Reportable patients are those seen face-to-face and *first registered* at the cancer center, whether as inpatients or outpatients, *during the reporting period*. All patients registered should be counted regardless of whether they have a newly diagnosed cancer or have recurrent disease and were referred to the cancer center for further evaluation and primary or secondary treatment occurring after the start date of the reporting period. This category *excludes* consults (e.g., for service or second opinions), diagnoses at autopsy, and former patients admitted for rehabilitation purposes or treatment of some other conditions. It also excludes patient follow up activities after treatment is completed.

Include data from affiliated institutions if agreements with the affiliates are sufficiently strong so as to guarantee that all their cancer patients will be reported to the center's registry. This would usually be the case, for example, with a children's hospital affiliated with a general university hospital, but would not apply to "satellite" institutions that submitted only a portion of their cancer patient population, or to patients whose only contact with the center was by virtue of being enrolled on protocol studies organized among community practitioners by center staff.

Therapeutic Trials: Clinical trials with **therapeutic** intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.

Table Format

Provide the total number of newly registered reportable patients by anatomical site of cancer for the selected reporting period, using the definitions above. Reflect the number of *patients* coming to the cancer center, not the numbers of visits. *Do not include any patient more than once unless they have two malignancies diagnosed in the same year*. Refer to the example format for Summary 3.

Provide the total number of inpatients and outpatients by anatomic site that were *newly placed* on therapeutic research protocols during the selected reporting period. Refer to the example format for Summary 3. A patient may appear more than once if he/she is on more than one therapeutic protocol during the reporting period. *Do not include patients on non-therapeutic trials.*

Outstanding University Cancer Center
Reporting Period mm/dd/yyyy – mm/dd/yyyy

Name of Reporting Source **Disease Site**	Newly Registered Patients	Total patients newly enrolled in **therapeutic** protocols
Lip, Oral Cavity and Pharynx		
Esophagus		
Stomach		
Small Intestine		
Colon		
Rectum		
Anus		
Liver		
Pancreas		
Other Digestive Organ		
Larynx		
Lung		
Other Respiratory and Intrathoracic Organs		
Bones and Joints		
Soft Tissue		
Melanoma, skin		
Kaposi's sarcoma		
Mycosis Fungoides		
Other Skin		
Breast – Female		
Breast – Male		
Cervix		
Corpus Uteri		
Ovary		
Other Female Genital		
Prostate		
Other Male Genital		
Urinary Bladder		
Kidney		
Other Urinary		
Eye and Orbit		
Brain & Nervous System		
Thyroid		
Other Endocrine System		
Non-Hodgkin's Lymphoma		
Hodgkin's Lymphoma		
Multiple Myeloma		
Lymphoid Leukemia		
Myeloid and Monocytic Leukemia		
Leukemia, other		
Leukemia, not otherwise specified		
Other Hematopoietic		
Unknown Sites		
Ill-Defined Sites		
TOTAL:		

International Classification of Diseases for Oncology

ICD-9-CM Codes and cross references to ICD-O-3 Codes to be used with Summary 3, Patient Information.

PRIMARY DISEASE SITE	ICD-9-CM [1]	ICD-O-3 [2]
Lip, Oral Cavity and Pharynx	140.0-140.6, 140.8, 140.9 141.0-141.6, 141.8, 141.9 142.0-142.2, 142.8, 142.9 143.0, 143.1, 143.8, 143.9 144.0, 144.1, 144.8, 144.9 145.0-145.6, 145.8, 145.9 146.0-146.9 147.0-147.3, 147.8, 147.9 148.0-148.3, 148.8, 148.9 149.0, 149.1, 149.8, 149.9	C000-C006, C008-C009, C019-C024, C028-C029, C030-C031, C039-C041, C048-C052, C058-C062, C068-C069, C079-C081, C088-C089, C090-C091, C098-C104, C108-C109, C110-C113, C118-C119, C129-C132, C139-C139, C140, C142, C148
Esophagus	150.0-150.5, 150.8, 150.9	C150-C155, C158-C159
Stomach	151.0-151.6, 151.8, 151.9	C160-C166, C168-C169
Small Intestine	152.0-152.3, 152.8, 152.9	C170-C173, C178-C179
Colon	153.0-153.9	C180, C182-C189, C199
Rectum	154.0, 154.1	C209
Anus	154.2, 154.3, 154.8	C210-C212, C218
Liver	155.0, 155.1	C220
Pancreas	157.0-157.4, 157.8, 157.9	C250-C254, C257-C259
Other Digestive Organ	156.0-156.2 159.0, 159.1, 159.8, 159.9	C221, C239-C241, C248-C249
Larynx	161.0-161.3, 161.8, 161.9	C320-C323, C328-C329
Lung	162.0, 162.2-162.5, 162.8, 162.9	C340-C343, C348-C349
Other Respiratory and Intrathoracic Organs	160.0-160.5, 160.8, 160.9 163.0, 163.1, 163.8, 163.9 164.0-164.3, 164.8, 164.9 165.0, 165.8, 165.9	C300, C301, C310-C313, C318-C319, C339, C379, C380, C381-C383, C384, C388, C390, C398-C399
Bones and Joints	170.0-170.9	C400-C403, C408-C414, C418-C419
Soft Tissue	158.0, 158.8, 158.9 171.0, 171.2-171.9	C470-C476, C478-C479, C480-C482, C488, C490-C496, C498-C499

Melanoma, skin	172.0-172.9	C440-C449
Kaposi's sarcoma	176.0-176.5, 176.8, 176.9	9140
Mycosis Fungoides	202.1	9700
Other Skin	173.0-173.9	8720-8790
Breast - Female	174.0-174.6, 174.8, 174.9	C500-C506, C508-C509
Breast – Male	175.0, 175.9	C500-C506, C508-C509
Cervix Uteri	180.0, 180.1, 180.8, 180.9	C530-C531, C538-C539
Corpus Uteri	182.0, 182.1, 182.8 179	C519, C540-C543, C548-C549, C559
Ovary	183.0	C569
Other Female Genital	181 183.2-183.5, 183.8, 183.9 184.0-184.4, 184.8, 184.9	C510-C512, C518-C519, C570-C574, C577-C579
Prostate	185	C619
Other Male Genital	186.0, 186.9 187.1-187.9	C600-C602, C608-C609, C620-C621, C629, C630, C631, C632, C637-C639
Bladder	188.0-188.9	C670-C679
Kidney	189.0, 189.1	C649
Other Urinary	189.2-189.4, 189.8, 189.9	C659, C669, C680-C681, C688-C689
Eye and Orbit	190.0-190.9	C690-C691, C692, C693, C694, C695-C698, C699
Brain and Nervous System	191.0-191.9 192.0-192.3, 192.8, 192.9	C700-C701, C709, C710-C714, C715, C716, C717-C719, C720-C725, C728-C729
Thyroid	193	C739
Other Endocrine System	194.0, 194.1, 194.3-194.6, 194.8, 194.9	C740-C741, C749, C750, C751-C752, C753, C754-C755, C758-C759
Non-Hodgkin's Lymphoma	200.0-200.2, 200.8 202.0, 202.8	9590-9591, 9596, 9670-9671, 9673, 9675, 9678-9680, 9684, 9687, 9689-9691, 9695, 9698-9699
Hodgkin's Lymphoma	201.0-201.2, 201.4-201.7, 201.9	9650-9655, 9659, 9661-9665, 9667

Multiple Myeloma	203.0, 203.1	9732-9733
Lymphoid Leukemia	204.0-204.2, 204.8, 204.9	9820, 9823, 9826-9828, 9832-9837
Myeloid and Monocytic Leukemia	205.0-205.3, 205.8, 205.9 206.0-206.2, 206.8, 206.9	9860-9861, 9863, 9866-9867, 9870-9876, and 9891, 9895-9897, 9910, 9920, 9930-9931
Leukemia, other	202.4 207.0-207.2, 207.8	9940, 9945-9946, 9948
Leukemia, not otherwise specified	208.0-208.2, 208.8, 208.9	9800-9801, 9805
Other Hematopoietic	202.3, 202.5, 202.6, 202.9 203.8 238.6, 238.7	9731, 9760-9762, 9740-9741, 9750, 9754-9758, 9950, 9960-9964, 9980, 9982-9987,9989
Unknown Sites	199.0, 199.1	C809
Ill-Defined Sites	195.0-195.5, 195.8	C760-C768

[1] The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9).

[2] International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3). Used principally in tumor or cancer registries for coding the site (topography) and the histology (morphology) of neoplasms, usually obtained from a pathology report.

Summary 4: Information on Clinical Research Studies

Using the example format for Summary 4, produce a report of the clinical research studies open at any time at your cancer center during the defined reporting period.

Name of Institution: Insert the name of the cancer center at the top of each page.

Reporting period: Insert the 12-month period for which data are being provided (as defined by the cancer center).

Sort the report in the following order according to the instructions below (also see sample format):

1. Clinical Research Category:

- clinical trials involving *an agent or device*;
- clinical trials involving *other types of intervention*s (i.e. behavioral modification, nutritional protocols, etc.);
- epidemiologic, outcome, or other observational studies;
- ancillary or correlative studies associated with a clinical trial and other biological studies using clinical specimens *that can be linked to individual patient or participant data***.**

2. Trial Sponsor (For clinical trials involving an agent or device or other intervention *only):*

- **National Cooperative Group Trials:** Place an asterisk [*] next to any trials authored by an investigator at your institution.
- **Other Externally Peer-Reviewed Trials:** R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations, such as the ACS, the Komen Foundation, etc. Place two asterisks [**] next to any multi-site trials authored by an investigator at your institution.
- **Institutional Trials:** In-house, internally reviewed trials, *including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.* Place two asterisks [**] next to any multi-site trials authored by an investigator at your institution.
- **Industrial Trials:** Design and implementation of the study is controlled by the pharmaceutical company.

3. Last name of the principal investigator, in alphabetic order

Table Format

Provide a column in the report, in the order provided, for each of the data items listed below:

Group/Sponsor/Funding Source: Provide the name of the external sponsor or funding source. For national group trials, use CALGB, CCG, ECOG, GOG, NSABP, POG, RTOG, and SWOG. For externally peer-reviewed trials or other clinical research studies, list the funding agency. For industrially sponsored research, **list the name of the pharmaceutical sponsor.** For institutionally sponsored trials or studies, list the names of the applicable funding agencies, including the parent institution, pharmaceutical company, or in the case of a multi-site study, the name of the other sponsoring cancer center.

Anatomic Site (Site): Identify the anatomic cancer site(s) (i.e. breast, ovary) on which the trial or study is focused. If a feasibility or early phase trial or other clinical study is broadly applicable to a number of potential anatomic sites, enter the term "multiple" in this column.

Protocol ID/IRB Number: Provide the unique identifier for this study. For both national and externally reviewed trials, list the common protocol number that the trial is known under nationally (if one exists), followed by the internal institutional number. For both institutional and industrial trials and other types of studies, use an internal protocol identification number or IRB number.

Principal Investigator (PI): Provide the **last name and first initial** of the Principal Investigator from your center who is responsible for this study.

Program (Prog): Provide the program code at your center that includes this protocol or study. **Use the codes defined in Summary 1B.**

Date Opened: Provide the date that this protocol or study was opened to accrual at your center.

Date Closed: If the protocol or clinical research study was closed to accrual at your center during the 12-month reporting period, provide the date it was closed.

Phase: For clinical trials, p**r**ovide the study phase. **Acceptable phases are pilot, feasibility, I, II, III, IV, or combinations such as I/II.** For epidemiologic, cancer control/behavioral, observational, ancillary, correlative or other biological studies, indicate "N/A."

Trial/Study Type (Type): Identify the type of trial or clinical research study, as follows:

- **Therapeutic (The) Trial:** Clinical trials with **therapeutic** intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.
- **Prevention (Pre) Trial:** Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.
- **Supportive Care (Sup) Trial:** Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.
- **Screening (Scr), Early Detection (Det), or Diagnostic (Dia) Trials:** Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.
- **Epidemiologic (Epi), Observational (Obs), or Outcome (Out) Trials:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
- **Ancillary (Anc) Trial:** Auxiliary studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies included must be linked to an active trial or epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patient or participant data should be reported.

- **Correlative (Cor) Trial:** Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Title: Provide a concise title for this trial or study (limited to 100 characters or fewer).

Target: Indicate the total number of patients or participants needed for the entire study (i.e. the targeted accrual) as stated in the protocol or study. Do **not** submit a targeted range, such as "10 – 100." If this is a multi-institutional or national trial authored by an investigator at another institution, cite only the number of patients or participants the cancer center expects to accrue over the next 12 months of the reporting period. If the center **initiated** the multi-site trial/study, enter both the number of patients or participants needed for the entire study across all participating sites (in parentheses), and the number of patients or participants to be accrued by the center during the next 12 months of the reporting period.

Accrual Site:

- **Cancer Center (Primary):** Create an accrual reporting column for patients involved in clinical trials at the primary hospital or treatment facility of the cancer center and healthy subjects involved in other clinical research at the cancer center.
- **Other (optional):** Create a separate patient/healthy subject accrual reporting column for all additional hospital or treatment facilities or research facilities closely associated with the cancer center (e.g., VA, Children's Hospital, other teaching hospital or research facility).

Accrual Timeframes:

- **12 Mos:** For each **applicable** accrual site reporting column, provide a count of the number of patients that were accrued to this trial or study during the identified 12-month reporting period.
- **To Date:** For each **applicable** accrual site reporting column, provide a count of the number of patients accrued to this trial to date. This is a cumulative figure, not an annual total.

Outstanding University Cancer Center

Reporting Period: mm/dd/yyyy – mm/dd/yyyy
Report Prepared: mm/dd/yyyy

SECTION 1 (Agent or Device)

NATIONAL											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
GOG	Cervix	106	Smith, J	5	1/25/00		II	The	Evaluation of Gemcitabine in Persistent or Recurrent Non-Squamous Cell Carcinoma of the Cervix	2	0	1	0	1
ECOG	Bladder	9638	*Saperstein, R	4	1/17/99		II	The	Study of Paclitaxel plus Carboplatin in patients with advanced carcinoma of the bladder	4	0	4	0	0

EXTERNALLY PEER-REVIEWED											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
NCI	Ovarian	9971	Ryabinsky, D	5	9/24/02		N/A	Dia	Detection of Ovarian specific markers in the peripheral blood in high risk women	50	2	8	10	10

INSTITUTIONAL											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
OUCC	Multiple	02-010	Booker, M	4	6/9/01		I	The	Ph 1 trial of subcutaneous and/or oral calciriol [(1,25-COH)2D3] and Carboplatin in advanced solid tumors	100	16	51	5	12

INDUSTRIAL											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
Superph	Leukemia	SP-990	Gonzalez, R	4	7/3/01		II	The	Genasense (Bcl-2 Antisense) combined with Mylotarg (gemtuzumab ozogamicin) in elderly patients with relapsed acute myeloid leukemia	5	0	1	1	1

SECTION 2 (Trials Involving other Interventions)

NATIONAL											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
ECOG	Prostate	CRJ-51	Harshman, A	4	1/7/95		Pilot	Sup	Randomized trial to study whether an outpatient educational and behavioral skills training program will improve pain control in patients who have metastatic or recurrent prostate cancer	225	15	191	19	19

EXTERNALLY PEER-REVIEWED											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
NCI	Multi	93-55	Prince, A	2	3/5/02		N/A	Pre	Teen smoking prevention and cessation via CD ROM program	500	46	210	0	0

INSTITUTIONAL											ACCRUAL			
Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
OUCC	Lip, Oral Cavity	3929	Collyer, E	2	9/7/00		N/A	The	Biobehavioral interventions for oral pain	70	13	13	6	23

SECTION 3 (Epidemiologic or other Observational Studies)

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
NCI	Ovarian	3315	Lemon, J	3	6/1/00		N/A	Epi	Exogenous hormone use and risk of ovarian cancer	55	12	49	2	5

SECTION 4 (Ancillary or Correlative Studies)

Sponsor	Site	Proto ID	PI	Prog	Date Opened	Date Closed	Phase	Type	Title	Target	Center 12 mos	Center To Date	Other 12 mos	Other To Date
GOG	Ovarian	D9902	Schubert, W	3	1/24/01		N/A	Anc	Protocol for collecting and banking ovarian cancer specimens	25	5	10	4	4

Summary 5: Comparison of Current and Requested CCSG Budgets

Using the attached format as a guide, provide the current CCSG budget (middle column), and the requested budget for the first year of the renewal application (right column) for each major budget category listed on the left. List the shared resources individually, as shown in the examples. Subcategorize developmental funds into recruitments, interim support, pilot projects, and new shared resources, etc. Show a sum of the total direct costs at the bottom of the chart.

The current budget, including the budget for each category and total direct costs, should reflect the last full year of the current competitive segment as submitted in the type 5 application and/or as detailed in the notice of award for that period, *exclusive of carryover funds and supplements*. The direct cost figures should include any third party indirect costs, since these are charged as direct costs to the CCSG.

Summary 5: Summary and Comparison of Current and Requested CCSG Budgets (Example Format) 2P30CA654321-50

Outstanding University Cancer Center

CCSG Budget Category	Current Budget (direct costs)* [insert date e.g., 01/01/0X– 12/31/0X] Last full year of current competitive grant	Requested Budget (direct costs) [insert date e.g., 01/01/0X – 12/31/0X] First full year of competitive application
Professional Personnel Senior Leadership Major Program Directors Staff Investigators Subtotal **Administration** **Planning & Evaluation** **Shared Resources and Services** Examples: Animal Facility Flow Cytometry Shared Resource Electron Microscope Shared Resource Etc. Subtotal **Protocol Review and Monitoring System** **Protocol Specific Research** **Developmental funds**		
Total Direct Costs		

***Exclusive of Carryover Funds and Supplements and inclusive of third party indirect cost**