P30 Cancer Center Support Grant
Data Guide

National Institutes of Health/ DHHS
National Cancer Institute
Office of Cancer Centers

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Bethesda, MD 20892-8345
http://cancercenters.cancer.gov/

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INTRODUCTION

Purpose

The purpose of the standard Cancer Center Information Data Tables is to ensure consistency and thoroughness in the peer review of competing applications. Additionally, the data are used to produce Data Table reports on the Cancer Centers Program.

Data Tables must be submitted annually according to application type as illustrated in the following table:

Table 1-1. Type of Application

Code	Type of Application	Submit Data Tables
Type 1 or 1A	New Competing or Amended	1-5
Type 2 or 2A	Competing Renewal or Amended	1-5
Type 3	Administrative Extension with Funds	1-4
Type 3	Administrative Extensions without Funds	Consult Program Director
Type 5	Non-Competing Continuation	1-4

Concurrent with the paper application submission, submit an electronic copy of the Data Table information, in Excel (.xls) format, directly to the Office of Cancer Centers at ccsgdata@mail.nih.gov. Please refer to CCSG Electronic Data Guide (eData) for more detail.

General Instructions for Data Tables:

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

References

The primary references related to this document are located on the following website: http://cancercenters.cancer.gov/grants_funding/index.html.

Site references:

- 2013 CCSG Guidelines and Data Table Information
- 2103 CCSG Electronic Data Table Format (eData)
- Summary of 2013 CCSG Data Table Changes
- FAQs

SECTION 1. DATA TABLES 1A, 1B, 1C, AND 1D

Introduction:

Data Table 1 lists the last name, first name, titles, and academic degrees of the Cancer Center's Senior Leaders, Program Leaders, and Shared Resource Directors. It also reports the Cancer Center's membership, names the Research Programs, and categorizes its Shared Resources.

Instructions and Example Formats:

1.1 Data Table 1A – Senior Leadership

For a center-defined reporting date, list the last name, first name, titles, and academic degree(s) of the senior leadership of the Cancer Center (*e.g.*, Cancer Center Director, Deputy Director, and Associate Directors). Indicate a change in leadership by inserting 'Yes' in the 'Is New Leader?' column.

Data Table 1A Example Format **2P30CA120212-09**

Outstanding University
Cancer Center Reporting Date: MM/DD/YYYY
Data Table 1A - Senior Leadership

Name of Senior Leader	Title of Leader	Degree(s)	Is New Leader?
Sutton, Baylor	Director and Principal Investigator	MD, PhD	
Marucco, Gina	Deputy Director	PhD	
Galley, Mark	Assoc. Director for Basic Science	MD	Yes
Barrie, Thomas	Assoc. Director for Clinical Research	MD, PhD	
Wong, Lee	Assoc. Director for Population Research	PhD	

1.2 Data Table 1B – Programs, Leaders, and Program Codes

For a center-defined reporting date, list the name of each Research Program and list the last name, first name, titles, and academic degree(s) of the Program Leader(s), and the number of members in the program. Assign a unique reference code of your choice (*e.g.*, 01, 02, or GYN, GU) to each program. Use the code ZY for non-programmatically aligned members. Indicate a change in leadership by inserting 'Yes' in the "Is New Leader?" column. Do not list developing programs or individual program members.

Data Table 1B Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 1 B – Programs, Leaders, and Program Codes

Program Code	Program Name	Program Leader(s)	Degree(s)	Is New Leader?	Is New Research Program?	Total # Members (including leader)
01	Molecular and Cellular Biology	Harrington, Marc	MD, PhD			25
02	Cancer Control and Prevention	Pham, Phuong	PhD		Yes	14
03	Epidemiology	Kaufman, Richard	MD, PhD			19
04	Developmental Therapeutics	Wood, Mary/ Storm, John	MD, PhD PhD			15
05	Women's Cancers	Miller, Barbara	PhD			22
CCGC	Cell Cycle and Growth Control	Neuhauser, Beverly	MD			12
IM	Immunology	Bhorjee, Jaswant	MD, PhD	Yes		27
ZY	Non-Aligned Members					12

Research Programs are peer-reviewed components of the CCSG. Therefore, they cannot be added or deleted during a non-competing year without prior approval from the NCI's Office of Cancer Centers. If your Center is considering a change in Programs during a non-competing year, please contact your Program Officer.

1.3 Data Table 1C – Cancer Center Membership

For a center-defined reporting date, provide the total number of programmatically aligned and non-programmatically aligned members, and the total number of all Cancer Center members. Cancer Center members in more than one Research Program should only be counted once.

Data Table 1C Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 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 Cancer Center Members (Individuals)	146

1.4 Data Table 1D – Shared Resources

For a center-defined reporting date, list the full name of each shared resource of the Cancer Center, and list the last name, first name, titles, and academic degree(s) of the resource director. For each shared resource, select up to three codes from the list titled "Categories of Shared Resources," that follows the example format below. Only include shared resources proposed for support by the CCSG. Indicate a change in leadership by inserting 'Yes' in the "Is New Leader?" column. Indicate developing cores supported with CCSG funds by inserting 'Yes' in the "Is Developing Resource?" column.

Data Table ID Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 1D: Shared Resources

Name of Shared Resource	Resource Director(s)	Degree(s)	Is New Leader?	Is New Resource?	Is Developing Resource?	Category
Biostatistics	Francini, Benjamin*	PhD	Yes			6.01
DNA Microarray	Poole, Bruce	MD			Yes	1.35
DNA Sequencing	Kelley, Steven	MD, PhD				1.22
Genomics and Proteomics	Goldstein, Phillip	MD		Yes		1.36
Bioinformatics	Mayrend, Jody	PhD				7.02
Organic Synthesis	Singer, Richard	MD, PhD	Yes			1.12
Transgenic Animal Facility	Peterson, Douglas/ Barns, Nancy	MD MD				1.03, 1.06, 1.09

Shared Resources are peer-reviewed components of the CCSG. Therefore, they cannot be added or deleted during a non-competing year without prior approval from the NCI's Office of Cancer Centers. If your Center is considering a change in Shared Resources during a non-competing year, please contact your Program Officer.

Table 1-2. Categories of Shared Resources

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	2.07 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	
4.03 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 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 Other (Define)	

SECTION 2. DATA TABLES 2A AND 2B – ACTIVE FUNDED PROJECTS

2.1 Data Table 2A – Active Funded Projects

Introduction:

Data Table 2A lists all active cancer-related research grants and contracts awarded by external sources to the fiscally responsible institution of which the Cancer Center is a part. It includes projects that have received a no-cost-extension.

Instructions and Example Format:

For a center-defined reporting date ("Active Funded Projects as of MM/DD/YYYY").

Organize Data Table 2A in alphabetical order by the principal investigator's last name and divide it into two parts:

- Projects that are awarded by NCI, NIH, or NCI-approved peer-review organization (see http://cancercenters.cancer.gov/documents/fundorg.pdf for a list of NCI –approved peer – reviewed funding organizations).
- Projects that are awarded by non-peer-review organizations

Divide both of the above into:

- Research Projects
- Training and career development grants
    - Identify all training grants, including the F, K, R25, and T series NIH grants, with the program code "T"

These divisions will create four, separate sections within Data Table 2A.

Note to Consortium Centers: Submit one Data Table 2A and 2B for the entire consortium.

General Instructions:

1. Enter the entire annual direct and annual total costs for the project/grant in the Project Dir Costs and Project Total Costs columns of the table.
2. Enter only the cancer-related (attributable-to-a-research-program) costs in the Program Dir Costs and Program Total Cost columns. For projects that are not entirely cancer-related, the Center should estimate the portion of the project that is cancer-related. For example, if two of four aims are cancer-related, the project could be considered 50%

cancer-related. These estimates are defined by the Center and should be defensible in peer-review.

3. For projects that are on a no-cost extension, list the unobligated balance figures in the annual Direct and total Project and Program Cost columns.
4. Include a subtotal and a grant total of the annual direct and total costs at the bottom of each table.

The column headings are defined as follows:

Principal Investigator (PI): The last name and first initial of the PI from your Center who is responsible for this project (*e.g.*, Alfred, L.)

Specific Funding Source: The specific name of the financial sponsor for the project (*e.g.*, NCI, ACS)

Project Number: Commonly referred to as the application number or grant number. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code [i] (*e.g.*, 1R01CA059736-01)

Project Start Date (Grant Start Date): Official date a grant award begins; same as the first day of the first budget period. (*e.g.*, 6/1/2010) [i]

Project End Date: Official date a grant award ends; same as the last day of the final budget period. (*e.g.*, 5/30/2015)

Project Title (Official Title): The official title of the research project being carried out at your institution (*e.g.*, Regulation of mitochondrial inheritance in yeast) [ii]

Annual Project Dir Costs: Annual Costs that can be identified specifically with a particular sponsored project or other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy [i]

Annual Project Total Costs: The total allowable annual costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity [i]

Program Code: An alphanumeric code that identifies Research Program affiliated with the clinical research study as defined by the Center in Data Table 1B (*e.g.*, 42, XY)

%: The proportion of research attributable to the identified Research Program

Annual Program Dir Costs: Annual Direct Costs that support research carried out in the Center's Research Programs

Annual Program Total Costs: Annual Total Costs that support research carried out in the Center's Research Programs

The following examples illustrate how funding can be distributed based of the type of project or grant:

Example 1: For individual projects awarded to a single investigator at your Center, list the grant in a single record. Indicate the annual direct and total Project and Program costs, the Project Start and End Date, the Project Title, the Program Code, and the proportion of research attributable to the identified Research Program in the "%" column. See the examples below.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Alfred L	NCI	1R01CA059736-01	6/1/2010	5/30/2015	Regulation of mitochondrial inheritance in yeast	$200,000	$260,000	4	100%	$200,000	$260,000
Christy W	ACS	RPG-96-045-04-1	1/1/2005	12/31/2010	The role of an HNF-3 protein in *c. elegans* foregut development	$104,000	$135,200	2	100%	$104,000	$135,200

Example 2: For individual projects awarded to a single investigator at your Center that is split among two or more research programs, list the grant in separate records for each program code, and the proportion attributable to each Research Program in the "%" column. Only list the Project annual Direct and Total Costs in one record. The sum of the percentages and dollars of any project assigned to different programs should not exceed 100%. See the examples below.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Dubois Y	NCI	5R01CA067893-02	9/1/2012	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)	$100,000	$130,000	1	60%	$60,000	$78,000
Dubois Y	NCI	5R01CA067893-02	9/1/2012	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)			5	40%	$40,000	$52,000

Example 3: For national trials authored by a PI at your Center, indicate the annual direct and total Project and Program costs only for funding to your Cancer Center. See the example below.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Cost	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Persky D	NCI	S1001	7/18/2011	6/30/2014	A Phase II Trial of R-CHOP followed by Yttrium-90 Ibritumomab tiuxetan for Early Stage Diffuse Large B-cell Lymphoma	$215,000	$279,500	5	100%	$215,000	$279,500

Example 4: For multi-investigator grants (such as SPOREs) awarded to the Center, list the annual direct and total Project Costs for the whole grant. Then separately list each of the Projects and Cores awarded to your Center and assign the appropriate % effort and Program dir and tot costs to the corresponding Research Program or Core. List the multi-investigators grant PI's name first and the Research Program Leader/ Core Director's name second. See the Lee SPORE in Lung Cancer example below.
The non-programmatically aligned code, ZY, is used for any other miscellaneous research projects. A detailed example is included in Example 8.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer	$1,000,000	$1,300,000				
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 2: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer			2	100%	$250,000	$325,000
Lee R/ Grant U	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core C: Administration and Patient Advocacy			ZY	100%	$40,000	$52,000
Lee R/ Jackson A	NCI	5P40CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: Core A: Tissure Procurement, Pathology, and Bioinformatics			ZY	100%	$185,000	$240,500
Lee R/ Sherman W, Smith W	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 1: E2F's Impact on Therapeutic Efficacy			1	100%	$220,000	$286,000
Lee R/ Stuart, J	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: RRM1 in the Management of Lung Cancer			1	100%	$225,000	$292,500

Example 5: If only part of a project is carried out within the Center through a subcontract, reflect only the Center's portion.

1. List the annual direct and total Project and Program Costs subcontracted to your Center. Include the name of the subcontracting Institution in the Funding Agency column. Assign the appropriate % effort to the corresponding Research Program. The total percentage for such a project may be less than 100%.
2. For R01 and R01-like grants subcontracted to your Center, see the Donegan example below.
3. For multi-investigator grants (such as SPOREs and P01s) subcontracted to your Center, include each Project or Core led at your Center. See Farber Proj. 1 and Jones Core B below.
    a. Use a pound sign below the subcontracting institution's name to indicate this project is a subcontract.
    b. For multi-investigator grants, only list the name of the Research Program Leader/ Core Director at your Center.
        i. In the Donegan example, the R01 was awarded to an investigator at Dartmouth. Donegan, at your Center, received $50,000 in annual direct project costs. Of those costs, 20% were cancer-related and fit into Program 3.
        ii. In the P01 example, the P01 was awarded to an investigator at Case Western. Farber, at your Center, leads Project 1 and received $80,000 in annual direct project costs. Of those costs, 40% were cancer-related and fit into Program 3. Jones, at your Center, leads Core B and received $40,000 in annual direct project costs. Of those costs, 20% were cancer-related.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Donegan A	NHLBI Dartmouth #	3R01HL086850-03S2	8/1/2012	7/30/2013	Calpain and p120 catenin regulation of cadherin function	$50,000	$65,000	3	20%	$10,000	$13,000
Farber J	NHLBI Case Western #	2P01HL070149-10	6/1/2013	5/31/2018	MECHANISMS OF GVHD Proj 1: Human Minor Histocompatibility Antigens	$80,000	$104,000	3	40%	$32,000	$41,600
Jones J	NHLBI Case Western #	2P01HL070149-10	6/1/2013	5/31/2018	MECHANISMS OF GVHD Core B: Biostatistics Core	$40,000	$52,000	ZY	20%	$8,000	$10,400

Example 6: For grants utilizing the multiple PI mechanism (such as R01s and P01s):

Use an "&" after each investigator's name to denote the use of the multiple PI mechanism.

When all investigators are members of your Center, to ensure appropriate credit, create separate entries in Data Table 2A for each PI. List the annual direct and total Project and Program Costs, and the appropriate % of the project attributable to each Research Program.
In the example below, $480,000 of the cancer relevant, annual direct project costs were given to Isaac and $320,000 of the cancer relevant, annual direct project costs were given to News of those, 60% of Isaac's work fit into Program 2 and 30% of News's work fit into Program 3.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Isaac M & News H &	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus-Cancer Associations	$480,000	$624,000	2	100%	$480,000	$624,000
News H & Isaac M &	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus-Cancer Associations	$320,000	$416,000	3	100%	$320,000	$416,000

Example 7: If not all principal investigators of a multi-PI project are members of your Center, treat the grant like #5 above. List the PI at your Center first. Include the name of the other Institution(s) in the Funding Agency column. Allocate the appropriate portion of annual direct and total Project and Program Costs and % effort to the corresponding Research Program(s). The total percentage for such a project may be less than 100%. See the Birmann and Newton examples below.

1. In the Birmann example, Glick is a member of UAB's Cancer Center. $140,000 of the cancer-relevant annual direct project costs were awarded to Birmann and 20% of Birmann's project fit into Program 3.
2. In the Newton example, Fish is a member of UNC's Cancer Center. $480,000 of the cancer-relevant, annual direct project costs were given to Newton and 100% of Newton's work fit into Program 4.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Birmann B & Glick D &	NINDS UAB	3R01NS046045-03	3/1/2012	2/28/2017	Targeting the anti-apoptotic protein survivin in glioma	$140,000	$182,000	3	20%	$28,000	$36,400
Newton C & Fish F &	NCI UNC	2R01CA055747-06	9/1/2012	8/30/2015	Epidemiologic and Genetic Studies of Breast Cancer	$480,000	$624,000	4	100%	$480,000	$624,000

Example 8: Use the non-programmatically aligned code (ZY) to:

1. List any funded research projects or parts of projects not assigned to formal research Programs. See the Mellon example below.
2. List any other miscellaneous research assignments, such as instrumentation grants, cores of funded projects (See the Lee/ Grant SPORE Core C example) or SEER contract (See the Gordon, E example}, and the CCSG and its associated supplements. See the Smith and Murphy examples.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Smith K	NCI	5P30CA010518-42	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program	$2,500,000	$3,250,000	ZY	100%	$2,500,000	$3,250,000
Smith K	NCI	5P30CA010518-42S1	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program: CURE Supplement	$120,000	$156,000	ZY	100%	$120,000	$156,000
Murphy J	NCI	3P30CA022354-30S3	5/1/2013	4/30/2014	Cancer Center Support Grant: Community Health Educator	$140,000	$182,000	ZY	100%	$140,000	$182,000
Gordon E	NCI	TAS 75 0849	1/1/2012	12/31/2018	Surveillance, Epidemiology, and End Results Program	$400,000	$520,000	ZY	100%	$400,000	$520,000
Lee R/ Grant U	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core C: Administration and Patient Advocacy			ZY	100%	$4,000	$5,200
Mellon C	NIDDK	5R01DK053265-03	2/1/2013	1/31/2018	In vivo Selection for Stem Cell Gene Therapy	$600,000	$780,000	ZY	20%	$120,000	$182,000

Example 9: For accrual-based, industry-funded projects, the annual Project Dir and Total Costs should be based on the actual (or estimated) number of patients enrolled for the relevant year. See example below.

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Costs	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Pope B	Vical	N/A	7/1/2014	12/21/2016	Phase II Trial of Allovectin-7 for Metastatic Melanoma	$250,000	$325,000	4	100%	$250,000	$325,000

Data Table 2A Example Format 2P30CA120212-

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 2A – Active Funded Projects

PEER-REVIEW RESEARCH PROJECTS

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Cost	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Farber J	NHLBI Case Western #	2P01HL070149-10	6/1/2013	5/31/2018	MECHANISMS OF GVHD Proj 1: Human Minor Histocompatibility Antigens	$80,000	$104,000	3	40%	$32,000	$41,600
Jones J	NHLBI Case Western #	2P01HL070149-10	6/1/2013	5/31/2018	MECHANISMS OF GVHD Core B: Biostatistics Core	$40,000	$52,000	ZY	20%	$8,000	$10,400
Alfred L	NCI	1R01CA059736-01	6/1/2010	5/30/2015	Regulation of mitochondrial inheritance in yeast	$200,000	$260,000	4	100%	$200,000	$260,000
Alison S	Leukemia & Lymphoma Society	LLS 7080-06 / 7004-11	10/1/2005	9/30/2015	Experimental Therapeutics in CLL	$1,000,000	$1,300,000	4	100%	$1,000,000	$1,300,000
Birmann B & Glick D &	NINDS UAB	3R01NS046045-03	3/1/2012	2/28/2017	Targeting the anti-apoptotic protein survivin in glioma	$140,000	$182,000	3	20%	$28,000	$36,400
Christy W	ACS	RPG-96-045-04-1	1/1/2005	12/31/2010	The role of an HNF-3 protein in c elegans foregut development	$104,000	$135,200	2	100%	$104,000	$135,200
Donegan A	NHLBI Dartmouth #	3R01HL086850-03S2	8/1/2012	7/30/2013	Calpain and p120 catenin regulation of cadherin function	$50,000	$65,000	3	20%	$10,000	$13,000
Dubois Y	NCI	5R01CA067893-02	9/1/2012	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)	$100,000	$130,000	1	60%	$60,000	$78,000
Dubois Y	NCI	5R01CA067893-02	9/1/202	8/30/2017	Star trial (Tamoxifen vs. Raloxifene)			5	40%	$40,000	$52,000
Gordon E	NCI	TAS 75 0849	1/1/2012	12/31/2018	Surveillance, Epidemiology, and End Results Program	$400,000	$520,000	ZY	100%	$400,000	$520,000
Isaac M& News H &	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus-Cancer Associations	$480,000	$624,000	2	100%	$480,000	$624,000
John E & Sir P &	NSF	1205439	5/1/2012	4/30/2015	mHealth - Computing Infrastructure for Mobile Health and Wellness Monitoring	$600,000	$780,000	ZY	10%	$60,000	$78,000
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer	$1,000,000	$1,300,000				
Lee R	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 2: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer			2	100%	$250,000	$325,000
Lee R/ Grant U	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Core C: Administration and Patient Advocacy			ZY	100%	$40,000	$52,000

Lee R/ Jackson A	NCI	5P40CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: Core A: Tissure Procurement, Pathology, and Bioinformatics			ZY	100%	$185,000	$240,500
Lee R/ Sherman W, Smith W	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer Proj 1: E2F's Impact on Therapeutic Efficacy			1	100%	$220,000	$286,000
Lee R/ Stuart, J	NCI	5P50CA119997-04	3/1/2012	2/28/2017	SPORE in Lung Cancer: RRM1 in the Management of Lung Cancer			1	100%	$225,000	$292,500
Mellon C	NIDDK	5R01DK053265-03	2/1/2013	1/31/2018	In vivo Selection for Stem Cell Gene Therapy	$600,000	$780,000	ZY	20%	$120,000	$182,000
Murphy J	NCI	3P30CA022354-30S3	5/1/2013	4/30/2014	Cancer Center Support Grant: Community Health Educator	$140,000	$182,000	ZY	100%	$140,000	$182,000
News H & Isaac M &	NIAID	1R01AI051273-01	10/1/2013	9/30/2016	Novel Approaches to Detect Virus-Cancer Associations	$320,000	$416,000	3	100%	$320,000	$416,000
Newton C &.Fish F &	NCI UNC	2R01CA055747-06	9/1/2012	8/30/2015	Epidemiologic and Genetic Studies of Breast Cancer	$480,000	$624,000	4	100%	$480,000	$624,000
Persky D	NCI	S1001	7/18/2011	6/30/2014	A Phase II Trial of R-CHOP followed by Yttrium-90 Ibritumomab tiuxetan for Early Stage Diffuse Large B-cell Lymphoma	$215,000	$279,500	5	100%	$215,000	$279,500
Sir P& John E &	NSF	1205439	5/1/2012	4/30/2015	mHealth - Computing Infrastructure for Mobile Health and Wellness Monitoring	$628,000	$816,400	1	10%	$62,800	$81,640
Smith K	NCI	5P30CA010518-42	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program	$2,500,000	$3,250,000	ZY	100%	$2,500,000	$3,250,000
Smith K	NCI	5P30CA010518-42S1	4/1/2011	3/31/2016	Consolidated Basic Cancer Research Program: CURE Supplement	$120,000	$156,000	ZY	100%	$120,000	$156,000
			Peer-Review Research Subtotals:			$9,197,000	$11,956,100			$7,299,800	$9,515,740

PEER-REVIEW TRAINING PROJECTS

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Cost	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Hay J	DOD	DAMD1702-1-11	9/1/2013	8/31/2015	Molecular study of bag domains: A new motif in prostate cancer	$45,000	$58,500	T	100%	$45,000	58,500
Kahl C	NHLBI	5F32HL069595-02	7/1/2010	6/30/2013	Differentiation of a stem cell population in vivo	$36,000	$46,800	T	50%	$18,000	23,400
Larson A	NHLBI	5K08HL001711-04	2/1/2012	1/30/2015	Serotonergic mechanisms is stress and anxiety	$170,000	$221,000	T	20%	$34,000	44,200
Jones B	NCI	1T32CA009579-01	5/1/2008	4/30/2013	Cell adhesion and effects on cell behavior	$25,000	$32,500	T	100%	$25,000	32,500
			Peer-Review Training Subtotals:			$276,000	$358,800			$122,000	$158,600

NON-PEER-REVIEW RESEARCH PROJECTS

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Cost	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Miller L	Breast Cancer Res. Fdn.	3568	10/1/2010	9/30/2015	Breast cancer prevention through nutrition program	$1,100,000	$1,430,000	2	100%	$1,100,000	$1,430,000
Norris C	Am.-Italian Cancer Foundation	4786	7/1/2012	6/30/2017	MicroRNAs as predictors of (pre)malignant phenotype in cystic neoplasms of the pancreas	$90,000	$117,000	1	90%	$81,000	$105,300
Pope B	Vical	N/A	7/1/2014	12/21/2016	Phase II Trial of Allovectin-7 for Metastatic Melanoma	$250,000	$325,000	4	100%	$250,000	$325,000
			Non-Peer-Review Research Subtotals:			$1,440,000	$1,872,000			$1,431,000	$1,860,300

NON-PEER-REVIEW TRAINING PROJECTS

PI	Specific Funding Source	Complete Project Number	Project Start Date	Project End Date	Project Title	Annual Project Dir Cost	Annual Project Total Costs	Prog Code	%	Annual Program Dir Costs	Annual Program Total Costs
Dinh H	ASCO	123	9/1/2011	8/31/2013	Enhancing Donor Cell Engraftment with CXCR4 Antagonist in Hematopoietic Stem Cell Transplantation	$100,000	130,000	T	90%	$90,000	117,000
Roberts E	Prostate Cancer Foundation Young Investigator Award	987	3/1/2012	02/30/15	Calibration and evaluation of a gene expression signature predictive of dasatinib sensitivity	$23,000	29,900	T	100%	$23,000	29,900
Smith L	Bayer HealthCare Pharmaceut icals Inc	564	7/1/2013	6/30/2015	Reproductive Scientist Development Program	$75,000	97,500	T	80%	$60,000	78,000
			Non-Peer-Review Training Subtotals:			$198,000	$257,400			$173,000	$224,900
					Grand Totals	$11,111,000	$14,444,300			$9,025,800	$11,759,540

2.2 Data Table 2B – Active Funded Projects

Introduction:

This Data Table describes the total number of Research and Training projects and their annual direct and total costs. It is organized by funding agency.

Instructions and Example Format:

For a center-defined reporting date, list the total number of Research and Training projects and the sum of annual direct and total costs for each major funding agency category as follows: NCI, other NIH, other Peer and Non Peer-Reviewed Industry-sponsored and Other non-peer reviewed. Provide subtotals and a grand total where indicated.

Data Table 2B Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 2B – Active Funded Projects

Specific Funding Source	Project Dir Cost	Project Total Costs	Total Number of Projects
NCI Peer-Review Projects	$5,180,000	$6,734,000	13
Other NIH Peer-Review Projects	$1,916,000	$2,490,800	9
Other Peer-Review Projects	$2,377,000	$3,090,100	5
Subtotal Of Peer Reviewed Projects	**$9,473,000**	**$12,314,900**	**27**
Industry Non-Peer-Review Projects	$325,000	$422,500	2
Other Non-Peer-Review Projects	$1,313,000	$1,706,900	4
Subtotal Of Non Peer Reviewed Projects	**$1,638,000**	**$2,129,400**	**6**
Grand Total (All Projects)	**$11,111,000**	**$14,444,300**	**33**

SECTION 3. DATA TABLE 3 – NEWLY REGISTERED PATIENTS/PARTICIPATION OF PATIENTS IN INTERVENTIONAL TREATMENT TRIALS BY ANATOMIC CANCER SITE

Introduction and Definitions:

Data Table 3 is intended to provide reviewers with an overview, organized by anatomic cancer site, of 1) the number of cancer cases seen at the Cancer Center, and 2) the participation of the Center's patients in interventional treatment trials devoted to those anatomic sites.

For a center-defined 12-month reporting period, Data Table 3 therefore reports: 1) the number of patients newly registered at the Cancer Center, and 2) the number of patients newly enrolled in interventional treatment trials. As this is intended as an overview, anatomic sites have been grouped for ease of review.

Note to Reviewers: Accrual data in Data Table 3 and 4 do not correlate exactly and should not be directly compared.

Note to Consortium Cancer Centers and Cancer Centers with affiliated institutions: Submit separate Data Table 3 tables for each consortium partner and/or affiliated institution (*e.g.*, pediatric hospital) that is a formal component of the Cancer Center but maintains a separate cancer registry. Do not include loosely affiliated community partners.

Use the following definitions to complete the Data Table 3 table:

- **Name of Reporting Source:** For consortium centers or those will affiliated institutions, indicate the specific name of the reporting institution
- **Reporting Period:** The 12-month period as defined by the Cancer Center
- **Reportable Cancers:** Malignancies with an International Classification of Diseases for Oncology (ICD) behavior code of 2 or 3 should be reported, in accordance with the established requirements of registry standard setting organizations. Please refer to http://cancercenters.cancer.gov/documents/ICD9-508.pdf for the list of International Classification of Diseases for Oncology codes.
- **Newly registered patients:** Newly registered patients are those patients seen face-to-face and recorded in the Cancer Center's Cancer Registry for the first time for that diagnosis during the reporting period. They include inpatients and outpatients who: 1) are newly diagnosed and/or receiving first course of treatment at the Cancer Center, *i.e.*, equivalent to American College of Surgeons (ACoS) – defined analytic case codes 00 – 22 (http://www.facs.org/cancer/coc/fords/FORDS_for_2011_01012011.pdf; pages 91 and 92); or 2)) have recurrent or persistent disease and are referred to the Cancer Center for evaluation and treatment, *i.e.*, equivalent to ACoS-defined non-analytic code 32.

The Center should exclude:

- Consults (*e.g.*, second opinions), new patient appointments, diagnoses at autopsy, admission of former patients for rehabilitation purposes or treatment of some other conditions, and patient follow-up after treatment.
- Data from "satellite" institutions that do not report all cancer patients to the Cancer Center's registry (see note for consortium and formal center partners above).
- Data on patients whose only contact with the center is due to enrollment on protocol studies organized among community practitioners by Cancer Center staff.

Do not include any patient more than once unless they have two malignancies in the same year.

A Cancer Center without access to a local or institutional registry should use alternate means to capture data as close as possible to the above definition.

- **Total patients newly enrolled in interventional treatment trials:** Interventional treatment trials are protocols designed to evaluate one or more interventions (*e.g.*, drugs, radiation, surgery, biological agents, devices, behaviors, etc.) for treating a disease, syndrome, or condition**.**

Note: This equates to therapeutic trials in the previous versions of the guidelines.

Include a patient more than once if he/she participated in more than one interventional treatment trial during the reporting period.

Instructions and Example Format:

Define a twelve-month reporting period.

For the selected reporting period, list the total number of newly registered patients and the total number of patients newly enrolled in interventional treatment trials by anatomic site.

Note: Data in these two columns should match in terms of their institutional source populations, following the criteria stated above. They should reflect the number of patients, not the number of visits.

Data Table 3 Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Period MM/DD/YYYY – MM/DD/YYYY
Data Table 3 – Newly Registered Patients /Participation in Interventional Treatment Trials by Anatomic Cancer Site

Name of Reporting Source **Primary Site***	**Newly Registered Patients**	**Total Patients newly enrolled in interventional treatment trials**
Lip, Oral Cavity and Pharynx	85	0
Esophagus	62	3
Stomach	181	4
Small Intestine	0	0
Colon	728	17
Rectum	50	10
Anus	9	0
Liver	121	6
Pancreas	52	8
Other Digestive Organ	174	8
Larynx	50	2
Lung	1257	50
Other Respiratory and Inthrthoracic Organs	105	18
Bones and Joints	25	6
Soft Tissue	35	3
Melanoma, skin	81	15
Kaposi's sarcoma	21	0
Mycosis Fungoides	23	0
Other Skin	6	1
Breast – Female	1203	54
Breast – Male	1	0
Cervix	60	5
Corpus Uteri	602	35
Ovary	49	1
Other Female Genital	33	0
Prostate	382	17
Other Male Genital	22	0
Urinary Bladder	188	12
Kidney	183	1
Other Urinary	10	1
Eye and Orbit	6	0
Brain & Nervous System	932	269
Thyroid	188	0
Other Endocrine System	21	0
Non-Hodgkin Lymphoma	190	41
Hodgkin Lymphoma	10	0
Multiple Myeloma	307	141
Lymphoid Leukemia	37	26
Myeloid and Monocytic Leukemia	154	111
Leukemia, other	1	0
Other Hematopoietic	83	37
Unknown Sites	118	0
Ill-Defined Sites	3	13
TOTAL:	**7945**	**924**

SECTION 4. DATA TABLE 4 – INFORMATION ON CLINICAL RESEARCH STUDIES

Introduction and Definitions:

Data Table 4 serves as a report of the clinical research studies open at your Cancer Center during a center-defined 12-month reporting period. Use the following definitions to complete Data Table 4.

Clinical Research includes:

- Patient oriented research: This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (*e.g.*, retrospective chart reviews). Patient-oriented research includes [iii]
    - Studies of mechanisms of human disease,
    - Studies of therapies or interventions for disease,
    - Clinical trials, and
    - Studies to develop new technology related to disease.
- Epidemiological and behavioral studies: 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.
- Health services research: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.[iv]

Accrual: The number of participants that have completed or are actively in the process of completing the study. This number includes dropouts. It does not include screen failures.

Multi-site Clinical Research Study: Clinical Research Studies that recruit participants from two or more geographically distinct enrollment sites not affiliated with your cancer center (*e.g.*, NCI-designated Cancer Centers or other research institutions). The sites are usually distinct in other characteristics (*e.g.*, demographic, socioeconomic, or clinical).

Instructions and Example Format:

On each page of Data Table 4, include the name of your Cancer Center and the 12-month data reporting period.

Determine whether the Clinical Research Study fits the NIH definition of Clinical Research. Then sort the studies by 1) Clinical Research Category, and 2) Study Source.

Note to Consortium Centers: Submit one Data Table 4 for the entire consortium.

Clinical Research Categories [iv]:

Interventional (INT): Clinical Research Category in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

Observational (OBS): Clinical Research Category in which the studies focus on cancer patients and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

Ancillary or Correlative (ANC/ COR):

- **Ancillary:** studies 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 must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.
- **Correlative:** 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.

Table 4-1. Clinical Research Category Mapping

Previous Clinical Research Category	Newly Defined Clinical Research Category
1: Agent or Device	INT
2: Trials Involving other Interventions	INT
3: Epidemiologic or other Observational Studies	OBS
4: Ancillary or Correlative Studies	ANC/COR

Study Source [iv]:

- **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks
- **Externally Peer-Reviewed:** R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or an approved peer-reviewed funding organization[4]

- **Institutional:** In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results
    - It is acceptable for industry and other entities to provide support (*e.g.*, drug, device, other funding) but the trial should clearly be the intellectual product of the center investigator.
    - This category may also include:
        - Institutional studies authored and implemented by investigators at another Center
        - Multi-site institutional studies authored and implemented by investigators at your Center
- **Industrial:** The design and implementation of these clinical research studies is controlled by the pharmaceutical company

Once the data are sorted by Clinical Research Category and Study Source, (*e.g.*, INT National; INT Externally Peer-Reviewed; INT Institutional; INT Industrial; OBS Peer-Reviewed; ANC/COR Externally Peer Reviewed) populate a table similar to the sample Data Table 4 table below. Sort the table alphabetically by PI.

Note: List the Study Source for each Clinical Research Category, including Observational and Ancillary/Correlative studies.

The column headings are defined below:

Specific Funding Source: The specific name of the financial sponsor for the clinical research study. For institutionally sponsored trials or studies, list the name of the applicable funding agencies.

Anatomic Site: The anatomic cancer site(s) (*i.e.* breast, ovary) the clinical research study focuses on. If the clinical research study is broadly applicable to a number of potential anatomic sites, enter the term "multiple" in this column.

Protocol ID/IRB Number (Proto ID): 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. For other types of trials, use an internal protocol identification or IRB number. [ii]

Principal Investigator (PI): The last name and first initial of the Principal Investigator from your Center who is responsible for this Clinical Research Study

Program (Prog Code): An alphanumeric code that identifies the Research Program affiliated with the clinical research study as defined by the Center in Data Tables 1B and 2A.

For clinical research studies that span more than one Research Program, include both Program Codes in this column. See the Falls, R. example.

Date Opened (activation): The official start date of a trial determined as follows 1) the date of activation noted in an official clinical trial activation announcement or 2) date of first

patient accrual if the trial in question did not have a formal activation announcement. [iv]

Date Closed: The date the clinical research study closed to accrual. If the study is still open, leave this field blank

Phase: For Interventional studies acceptable phases include: pilot, feasibility, 0, 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." [iv]

Primary Purpose: [iv]

Diagnostic (DIA): Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.

Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Other (OTH): Not in other categories

Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

Screening (SCR): Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

Supportive Care (SUP): Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.

Basic Science (BAS): Protocol designed to examine the basic mechanisms of action (*e.g.*, physiology, biomechanics) of an intervention.

Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in the previous versions of the guidelines.

Table 4-2. Study Type Mapping

Previous Study Type Designations	New Primary Purpose Designations
The	Tre
Pre	Pre
Sup	Sup
Scr/Det/Dia Src Det Dia	 Scr Scr or Dia (depending on the nature of the study) Dia
Epi/Obs/Out	Oth
Anc	Oth or Bas (depending on the nature of the study)
Cor	Bas
(No existing comparable Study Type)	Hsr

Official Title: Official name of the protocol provided by the study principal investigator or sponsor (Limit: 600 characters or fewer). [ii]

Multi-Institutional trials: Indicate whether the trial is multi-site by inserting 'Yes' or 'No' in the 'Is Multi-Inst?' column.

Total Targeted Accrual: For both single-site and multi-site trials initiated at your Center, indicate the total number of participants needed for the entire study. For multi-site trials that your Center participates in but did not initiate, leave this column empty. Do not submit a targeted range, such as "10 – 100." See Examples 1 – 3.

Targeted Accrual for your Center: For single-site and multi-site trials initiated at your Center, indicate the total number of participants your Center is expected to accrue for the study. For single-site trials the "Total Accrual for your Center" and the "Total Targeted Accrual" numbers will be the same. Do not submit a targeted range, such as "10 – 100." See Examples 1 – 3 below.

Accrual Sites:

- **Cancer Center Primary Accrual Site:** List the number of participants enrolled in the clinical research study at the Cancer Center, including formal Consortium Partners. [v]
- **Other Accrual Sites:** List the number of participants enrolled in the clinical research study at all hospitals, treatment facilities, and/ or research facilities that are not a formal part of the Cancer Center (*e.g.*, nearby community hospitals or other Centers that are participating in multi-site trials led by your Cancer Center).

Accrual Timeframes:

- **12 Month Reporting Period:** Provide the number of participants accrued to this clinical research study during the identified 12-month reporting period.
- **To Date:** Provide the number of participants accrued to this clinical research study to date. This number is a cumulative figure, not an annual total.

Notes:

1. For trials initiated and accruing patients only at your Center, the number of patients in the "Entire Study" and "Your Center" Total Targeted Accrual columns should match. Enter the actual number of accruals in the "Cancer Center: Primary Accrual Site" columns. Leave the "Other Accrual Sites" columns blank.
2. For trials initiated and accruing patients at both your Center and additional sites, all columns under the "Total Targeted Accrual", "Cancer Center: Primary Accrual Site", and "Other Accrual Sites" should be filled in.
3. For trials that your Center accrues to but did not initiate, leave the "Entire Study" column blank. Enter the Total Targeted Accrual for Your Study. Enter the actual number of accruals in the "Cancer Center: Primary Accrual Site" columns. Leave the "Other Accrual Sites" columns blank.

If the data is not available or applicable, leave the column empty.

The following examples illustrate how to report Data Table 4 data:

Example 1: If your Cancer Center initiated the clinical research study and it only takes place at your Cancer Center and its formal consortium partners (single site):

1. Enter the total number of participants needed for the entire study twice; once in the "entire study" column and once in the "Your Center" Total Targeted Accrual column
2. Enter the number of participants the Center accrued during the past 12 month reporting period in the "Cancer Center 12 months" column
3. Enter the number of participants the Center has accrued to date in the "Cancer Center to Date" column
4. Leave the Other Accrual Sites columns empty
5. See the example below

Interventional:

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other: Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NYU	Multiple	NYU 0521	Hook, S.	10	1/17/2013		II	Sup	Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT	No	105	105	10	30		

Example 2: If your Cancer Center initiated the clinical research study and it takes place at your Center and other accrual sites (multi-site):

1. Enter the total number of participants needed for the entire study in the "Entire Study" Total Targeted Accrual column
2. Enter the total number of participants your center expects to accrue over the duration of the study in the "Your Center" Total Targeted Accrual column
3. Follow instructions 2-3 in Example 1 above.
4. Enter the number of participants the other sites have accrued during the past 12 month reporting period in the Other 12 months column
5. Enter the number of participants the other sites have accrued to date in the "Other to Date column"
6. See the Mack, F. example below

Interventional:

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other: Accrual Site(s)	
Specific Funding Source	Anatomic Site	Proto ID	PI	Prog Code	Date Opened	Date Closed	Phase	Primary Purpose	Official Title	Is multi-Inst trial?	Entire Study	Your Center	12 Mos	To Date	12 Mos	To Date
NYU, NCI	Multiple	NCI - 1109	Mack, F.	3	8/1/2012		III	Sup	Preparatory Aid to Improve Decision Making about Cancer Clinical Trials (PRE- ACT)	Yes	400	60	22	46	70	240

Example 3: If the Cancer Center is participating in a multi-institutional, national clinical research study or a study initiated by another Institution:

1. Leave the "Entire Study" column empty
2. Enter the total number of participants your center expects to accrue over the duration of the study in the "Your Center" Total Targeted Accrual column
3. Follow instructions 2-4 in Example 1 above.
4. See the example below

Interventional:

NATIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
COG	Myeloid leukemia	COG-08H9	Lehr, D.	4	5/1/2012		I	Tre	Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia	Yes		6	0	4		

Data Table 4 Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Period: MM/DD/YYYY – MM/DD/YYYY
Report Prepared: MM/DD/YYYY
Data Table 4 – Clinical Research Protocols

Interventional:

NATIONAL											Total Targeted Accrual		Cancer Center Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
RTOG	Bladder	RTOG 0712	Armstrong, C.	2	8/15/2013		III	Tre	Randomized chemo/rt/surg for bladder cancer	Yes		220	82	120		
CALGB	Myeloid leukemia	10603	Kane, S.	8	4/21/2012		III	Tre	Induction & Consolidation Chemo + Midostaurin v Placebo in Newly Diagnosed FLT3 Mutated AML	Yes		70	28	49		
COG	Myeloid leukemia	COG-08H9	Lehr, D.	4	5/1/2012		I	Tre	Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia	Yes		6	0	4		

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NYU, NCI	Multiple	NCI - 1109	Mack, F.	3	8/1/2012		III	Sup	Preparatory Aid to Improve Decision Making about Cancer Clinical Trials (PRE-ACT)	Yes	400	60	22	46	70	240
NCI	Colon, Rectum	NCI 06-8-01	Shephe ard, A.	2	12/5/2014		II	Pre	Polyethylene Glycol For ACF Reduction and Biomarker Modulation in Individuals with CRC Risk	No	140	140	34	68		

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NYU	Breast	NYU-1054	Allen, T.	2	2/14/2013		I/II	Sup	Dose Finding and Tolerability ALA in Paclitaxel Induced Neuropathy Pts.	No	30	30	4	10		
NYU	Lymphoma	NYU-5150	Bates S.	4	5/1/2012		I	Tre	Ofatumumab for inindolent B-cell lymphomas	Yes	10	6	0	4	2	4
NYU	Multiple	NYU-1133	Dunn, R.	1	7/4/2015		II	Pre	Restasis Vs Placebo in Primary Prevention of Ocular GVHD	Yes	14	6	2	5	2	8
NYU	Multiple	NU-0521	Hook, S.	10	1/17/2013		II	Sup	Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT	No	105	105	10	30		

INDUSTRIAL											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
GSK	Leukemia	GSK 0806	Day, P.	10	3/1/2013		I	Sup	Phase 1 Trial of Palifermin for Oral Mucositis	Yes	15	15	6	8		
BMS	Lymphoid leukemia	DRUG 5013	Head, R.	8	5/1/2014		III	Tre	Lenalidomide as Maintenance Therapy for Patients with B-cell CLL	No		113	47	79		

Observational:

EXTERNALLY PEER-REVIEWED											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NCI	Brain and Nervous System	NCI-2902	Falls, R.	8 & 10	7/2/2012		N/A	Oth	Neurocognitive outcomes in pediatric brain tumor survivors following proton beam XRT vs conventional XRT	No	100	100	13	30		
American Cancer Society	Prostate	ACS-2162	Rogers, S.	6	9/5/2014		N/A	Oth	Focus group evaluation of prostate cancer symptom management education materials	Yes	30	14	6	8	7	14
NCI	Ovarian	NCI-3315	Lemon, J.	3	6/1/2013		N/A	Oth	Exogenous hormone use and risk of ovarian cancer	No		50	12	49		

INSTITUTIONAL											Total Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NYU	Multiple	NYU-1926	Berry, J.	08	5/1/2015		N/A	Oth	Risk factors for childhood cancer and hematological disorders by case-control studies	**Yes**	4000	1500	125	499	86	600
NYU, NIH	Multiple Myeloma	NYU-1007	Smith, S	08	1/1/2010	4/7/2011	N/A	Oth	Treatment Decision Making in Older Adults Newly Diagnosed with MM	No		20	6	18		

Ancillary or Correlative:

INSTITUTIONAL											Tota Targeted Accrual		Cancer Center: Primary Accrual Site		Other Accrual Site(s)	
Specific Funding Source	**Anatomic Site**	**Proto ID**	**PI**	**Prog Code**	**Date Opened**	**Date Closed**	**Phase**	**Primary Purpose**	**Official Title**	**Is multi-Inst trial?**	**Entire Study**	**Your Center**	**12 Mos**	**To Date**	**12 Mos**	**To Date**
NYU	Brain	NYU -1762	Okra, S.	08	2/23/2016		N/A	Bas	Phase I & 2 drug metabolism polymorphisms & outcome in children with medulloblastoma	No	54	54	10	36		
NYU	Leukemia	NYU-2701	Granger, I.	08	6/15/2010		N/A	Bas	Prospective observational trial of telomere length and telomerase mutations in pediatric AML	Yes	50	30	12	25	8	18
NYU	Leukemia	NYU -0631	Down, R.	08	2/30/2014		III	Oth	Comparison of Acute and Long-term Toxicities in BM Donors w/wout G- CSF Treatment Prior to Harvest	No		206	48	89		
NYU	Other hemapoietic	NYU-0898	Gosden, R.	08	2/4/2015		N/A	Bas	Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS)	No		17	1	3		

SECTION 5. DATA TABLE 5 – COMPARISON OF CURRENT AND REQUEST CCSG DIRECT COST BUDGETS

Introduction:

For a center-defined reporting date, this Data Table compares the Cancer Center's current budget to its requested budget.

Instructions and Example Format:

For Type 1 and 2 applicants:

Using the format below as a guide, provide the current direct cost CCSG budget (Type 2 only), and the requested budget for the first year of the new competitive project period (both Type 1 and Type 2) for each major budget category listed on the left. List non-salary funds for Research Programs separately, and list the shared resources individually. List only the total for Developmental Funds. Show a sum of all the direct costs at the bottom of the chart.

The current budget should reflect the last full year of the current competitive project period 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.

Data Table 5 Example Format **2P30CA120212-09**

Outstanding University Cancer Center
Reporting Date: MM/DD/YYYY
Data Table 5 – Data Table and Comparison of Current and Requested CCSG Budgets

CCSG Budget Category	Current Budget (direct costs)***** Insert a Date Range (*e.g.*, 01/01/YY– 12/31/YY) Last full year of the current competitive project period	Requested Budget (direct costs) Insert a Date Range (*e.g.*, 01/01/YY – 12/31/YY) First full year of the new competitive project period
Professional Personnel		
Senior Leadership		
Program Leaders		
Research Programs (non-salary)		
Cancer Biology		
Experimental Therapeutics		
Administration		
Planning & Evaluation		
Shared Resources and Services		
Flow Cytometry		
Biostatistics		
Clinical Protocol and Data Management		
Protocol Review and Monitoring System (PRMS)		
Early Phase Clinical Research Support		
Developmental funds		
Total Direct Costs		

*****Data Table 5 includes third party indirect costs. It does not include CCSG carryover funds or CCSG supplement dollars.

END NOTES

[i] http://grants.nih.gov/grants/glossary.htm

[ii] http://prsinfo.clinicaltrials.gov/definitions.html

[iii] http://grants.nih.gov/grants/policy/hs/glossary.htm

[iv] http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources/glossary

[v] As defined in the "Policies and Guidelines Relating to the P30 Cancer Center Support Grant" document Section 1.7, Consortium Centers