P30 Cancer Center Support Grant Data Table Guide 2.0

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

9609 Medical Center Drive Rockville, MD 20850

http://cancercenters.cancer.gov/

INTRODUCTION

Purpose of the Data Tables

In competing applications (Types 1 and 2), Data Tables (DT) 1-5 facilitate consistency and thoroughness in review by providing peer reviewers with standardized information on center organization and leadership, active cancer-related research, and several aspects of clinical function.

In non-competitive applications (Types 3 and 5), electronic DT 1-4 (eData), submitted to the Office of Cancer Centers (OCC), are used to assess center progress, generate reports, and produce benchmark data on the Centers program.

Submission Types

Please use the following table to determine appropriate DT submission:

| Application Type | ASSIST | RPPR | eDATA (to OCC) |
|------------------|--------|------|--|
| 1 | DT 1-5 | None | None (DT 1-4 due if CCSG is awarded) |
| 2 | DT 1-5 | None | DT 1-4 (60 days prior to start date)* |
| 3 | None | DT 1 | DT 1-4 (60 days prior to start date) |
| 5 | None | DT 1 | DT 1-4 (60 days prior to start date) |

*Note: Per NIH policy, T2 applications serve as the progress report for the fiscal year in which the application is newly funded. Although no separate RPPR need be submitted 60 days prior to the start date of the newly funded award, DT 1-4 must still be submitted at that time.

eData Guide (http://cancercenters.cancer.gov/documents/eData-508.pdf) for instructions on format.

An FAQ document for further guidance is at available at http://cancercenters.cancer.gov/grants_funding/index.html.

General Instructions for DTs:

- 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
- It is permissible to have different reporting dates for the different DTs
- Follow the example formats provided

DT 1

DT 1A-D provide general information about the Senior Leadership, Research Programs, Cancer Center Membership, and Shared Resources.

For T2 applications, "New" in DT 1 refers to new since the last T2 application. For T3 and T5, "New" refers to new since the last T3 or T5 progress report.

DT 1A – Senior Leadership. For a center-defined reporting date, follow the format below to report the Senior Leadership:

2P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY Data Table 1A – Senior Leaders

| Name of Senior Leader | Title of Leader | Degree(s) | 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 | |

DT 1B – Research Programs. For a center-defined reporting date, define a center-selected alphanumeric code to denote each Research Program, and follow the format below to report the Research Programs:

2P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY Data Table 1B – Research Programs

| Program Code | Program Name | Program Leader(s) | Degree(s) | New Leader? | New Program? | Members |
|-----------------|-----------------------------------|-------------------------------|-----------|----------------|--------------|---------|
| 01 | Molecular and Cellular Biology | Harrington, Marc Cox, Michael | MD PhD | | | 25 |
| 02 | Cancer Control and Prevention | Pham, Phuong | PhD | Yes | Yes | 14 |
| 03 | Epidemiology | Kauman, John Jordon, Mark | MD PhD | Yes | | 19 |
| 04 | Prostate | Yeh, Grace | MD | Yes | | 26 |
| WC | Women's Cancers | Miller, Barbara | PhD | | | 22 |
| CCGC | Cell Cycle and Growth Control | Neuhauser, Beverly | MD | | | 12 |
| ZY | Non-aligned members | | | | | 9 |

Note: Include Program Leaders in number of members.

DT 1C – Cancer Center Membership. For a center-defined reporting date, follow the format below to report the Center's membership:

2P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY

Data Table 1B – Cancer Center Membership

| Type of Member | Total Number |
|---|--------------|
| Programmatically Aligned Members (Individuals) | 118 |
| Non-Programmatically Aligned Members (Individuals) | 9 |
| Grand Total - Total Number of Cancer Center Members (Individuals) | 127 |

Note: Members in more than one program should be counted once.

 $DT\ 1D$ – Shared Resources. For a center-defined reporting date, follow the format below to report the Shared Resources:

P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY Data Table 1D – Shared Resources

| Name of Shared Resource | Resource Director(s) | Degree(s) | New Leader? | New Resource? | Developing Resource? | Category |
|----------------------------|------------------------------------|-----------|----------------|---------------|----------------------|--------------------|
| Biostatistics | Francini, Benjamin | PhD | Yes | | | 6.01 |
| DNA Microarray | Poole, Bruce | MD | | | Yes | 1.35 |
| DNA Sequencing | Kelley, Mark | MD, PhD | | | | 1.22 |
| Genomics and Proteomics | Goldstein, Phillip | MD | | Yes | | 1.36 |
| Bioinformatics | Mayrend, Jody | PhD | | | | 7.02 |
| Vaccine Core | Mark, Joseph | PhD | | | | 1.37 |
| Organic Synthesis | Singer, Richard | PhD | Yes | | | 1.12 |
| Transgenic Animals | Peters, Douglas Rogers, Kate | PhD MD | | | | 1.03,1.06, 1.09 |
| Translational Chemistry | Hahn, Otto | PhD | Yes | | | 4.08 |

Notes:

- Report only CCSG-funded shared resources
- Developing shared resources are those that have not previously been peer-reviewed
- Select up to three category codes from the following table:

| 1.01 Biochemical Analysis 1.02 General Animal Facility 1.03 Transgenic Facility 1.04 Special Breeding 1.05 Animal Health (Pathology/Histology) 1.05 Animal Health (Pathology/Histology) 1.06 Animal Health (Pathology/Histology) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.09 Nude Mouse 1.10 Specialized Animal Sves (Irradiation) 1.10 Specialized Animal Sves (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 Electron Microscopy 1.19 General or Equipment Repair 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Florimal Research 4.03 Clinical – Other 4.03 Clinical - Other 4.04 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) 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) | Category 1: Laboratory Science | |
|---|--|---------------------------------------|
| 1.02 General Animal Facility | | 1 19 Cyclotron or Radiolabeling |
| 1.03 Transgenic Facility | | |
| 1.04 Special Breeding 1.05 Animal Health (Pathology/Histology) 1.06 Animal Health (Pathology/Histology) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.09 Nude Mouse 1.10 Specialized Animal Sves (Irradiation) 1.10 Specialized Animal Sves (Irradiation) 1.10 Specialized Animal Sves (Irradiation) 1.11 Biohazard Control 1.12 Organic & Synthetic Chemistry 1.13 Chromatography 1.13 Chromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Flow Cytometry 1.10 General or Equipment Repair 1.20 Machine Shop 2.08 Media Preparation 2.01 Glassware Washing 2.02 Machine Shop 2.03 Glassware Washing 2.04 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.05 Human Tissue Acquisition & 4.06 Human Tissue Acquisition & 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: Biostatistics Category 7: Informatics 7.04 Other (Define) Category 7: Informatics 7.04 Other (Define) Category 8: Miscellaneous | | |
| 1.05 Ánimal Health (Pathology/Histology) 1.06 Animal Health (QC) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.09 Nude Mouse 1.27 Spectrometry, Other (Specify) 1.10 Specialized Animal Svcs (Irradiation) 1.28 Radiobiology 1.19 Indiparated Control 1.19 Oligonucleotide Synthesis 1.12 Organic & Synthetic Chemistry 1.10 Protein/Peptide Synthesis 1.13 Orromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Electron Microscopy 1.19 Flow Cytometry 1.10 General or Equipment Repair 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Spidemiology 3.04 Survey 3.03 Epidemiology 4.05 Pharmacology (Lab Tests) 4.06 Human Tissue Acquisition & Pathology/Histology 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 7: Informatics 7.03 Public Health/Epidemiology Informatics 7.04 Other (Define) | | |
| 1.06 Animal Health (QC) 1.08 Specific Pathogen Free (Barrier Animal Facility) 1.09 Nude Mouse 1.27 Spectrometry, Other (Specify) 1.10 Specialized Animal Svcs (Irradiation) 1.18 Biohazard Control 1.19 Organic & Synthetic Chemistry 1.10 Cyrganic & Synthetic Chemistry 1.11 Cyrology-Analytic & Immunologic 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Froteomics 1.18 Flow Cytometry 1.19 General or Equipment Repair 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.03 Glassware Washing 2.04 Guerer Control 3.05 Nutrition 3.05 Epidemiology 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical - Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.03 Public Health/Epidemiology Informatics 7.04 Other (Define) Category 8: Miscellaneous | | |
| 1.08 Specific Pathogen Free (Barrier Animal Facility) | | |
| 1.09 Nude Mouse | | - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - |
| 1.10 Specialized Animal Svcs (Irradiation) 1.11 Biohazard Control 1.12 Organic & Synthetic Chemistry 1.13 Chromatography 1.13 Chromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Content Peptide Synthesis 1.31 Toxicology/Mutagenesis Testing 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Category 2: Laboratory Support 1.19 General or Equipment Repair 2.01 General or Equipment Repair 2.02 Machine Shop 2.08 Media Preparation 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.03 Public Health/Epidemiology Informatics 7.04 Other (Define) | | |
| 1.11 Biohazard Control 1.12 Organic & Synthesis 1.12 Organic & Synthetic Chemistry 1.31 Chromatography 1.31 Toxicology/Mutagenesis Testing 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Electron Microscopy 1.19 Category 2: Laboratory Support 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Spidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.03 Public Health/Epidemiology Informatics 7.04 Other (Define) Category 8: Miscellaneous | | |
| 1.12 Organic & Synthetic Chemistry 1.13 Chromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 Cytogenetry 1.20 Machine Shop 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: 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 | | |
| 1.13 Chromatography 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.17 Electron Microscopy 1.17 Electron Microscopy 1.18 Flow Cytometry 1.19 General or Equipment Repair 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Lab Tests) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: 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 | | |
| 1.14 Cytology-Analytic & Immunologic 1.15 Cytogenetics 1.16 Genetics 1.16 Genetics 1.17 Electron Microscopy 1.18 Flow Cytometry 1.18 Flow Cytometry 1.19 Category 2: Laboratory Support 2.01 General or Equipment Repair 2.02 Machine Shop 2.08 Media Preparation 2.09 Media Preparation 2.00 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.02 Epidemiology 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.03 Flore Circle (Define) Category 8: Miscellaneous | | |
| 1.15 Cytogenetics 1.34 Xray Diffraction 1.16 Genetics 1.35 DNA Array 1.17 Electron Microscopy 1.36 Proteomics 1.18 Flow Cytometry 1.37 Other (Define) Category 2: Laboratory Support 2.01 General or Equipment Repair 2.07 Tissue Culture 2.02 Machine Shop 2.08 Media Preparation 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.05 Nutrition 3.04 Survey 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical – Other 4.06 Human Tissue Acquisition & 4.04 Pharmacology (Animal) Pathology/Histology 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.03 Public Health/Epidemiology Informatics 7.02 Bioinformatics 7.04 Other (Define) | | |
| 1.16 Genetics | | |
| 1.17 Electron Microscopy 1.18 Flow Cytometry 1.37 Other (Define) Category 2: Laboratory Support 2.01 General or Equipment Repair 2.02 Machine Shop 2.08 Media Preparation 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.03 Public Health/Epidemiology Informatics 7.04 Other (Define) Category 8: Miscellaneous | | |
| Category 2: Laboratory Support 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.05 Nutrition 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 4.07 Gene Therapy/Vector 4.08 Other (Define) Category 6: Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 1.17 Electron Microscopy | |
| 2.01 General or Equipment Repair 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 1.18 Flow Cytometry | 1.37 Other (Define) |
| 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: 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 | Category 2: Laboratory Support | |
| 2.02 Machine Shop 2.03 Glassware Washing 2.10 Other (Define) Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: 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 | 2.01 General or Equipment Repair | 2.07 Tissue Culture |
| 2.03 Glassware Washing Category 3: Epidemiology, Cancer Control 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey 3.06 Other (Define) Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: 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 | | 2.08 Media Preparation |
| 3.01 Cancer Control 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 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 | | |
| 3.03 Epidemiology 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) 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 | Category 3: Epidemiology, Cancer Control | |
| 3.04 Survey Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 3.01 Cancer Control | 3.05 Nutrition |
| Category 4: Clinical Research 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics Category 8: Miscellaneous | 3.03 Epidemiology | 3.06 Other (Define) |
| 4.03 Clinical – Other 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 3.04 Survey | |
| 4.04 Pharmacology (Animal) 4.05 Pharmacology (Lab Tests) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | Category 4: Clinical Research | |
| 4.05 Pharmacology (Lab Tests) 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 7.04 Other (Define) Category 8: Miscellaneous | | |
| 4.08 Other (Define) Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 4.04 Pharmacology (Animal) | |
| Category 6: Biostatistics 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 4.05 Pharmacology (Lab Tests) | 4.07 Gene Therapy/Vector |
| 6.01 Biostatistics Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | | 4.08 Other (Define) |
| Category 7: Informatics 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | Category 6: Biostatistics | |
| 7.01 Clinical Research Informatics 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | 6.01 Biostatistics | |
| 7.02 Bioinformatics 7.04 Other (Define) Category 8: Miscellaneous | Category 7: Informatics | |
| Category 8: Miscellaneous | 7.01 Clinical Research Informatics | |
| ~ 1 | 7.02 Bioinformatics | 7.04 Other (Define) |
| 8.01 Other (Define) | Category 8: Miscellaneous | |
| | 8.01 Other (Define) | |

DT 2A and 2B

DT 2A and 2B report 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.

DT 2A

- Define a reporting date and include cancer-related grants and contracts that are active as of that date, including those in no-cost extension.
- Organize Data Table 2A into four separate tables: peer-reviewed research projects, peer-reviewed training projects, non-peer-reviewed research projects, and non-peer-reviewed training projects. Label each table. Peer-reviewed projects are defined as those awarded by NCI, NIH, or organizations listed here:
 http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf
- Report projects in alphabetical order within each table by the principal investigator's (PI) last name, or overall PI's name for multi-component projects.
- Report only grants and contracts that are awarded by external sources to the fiscally
 responsible institution of which the Center is a part, and whose PI is a Cancer Center
 member. Thus, grants and contracts that flow to other institutions, even if the PI is a
 member of the Center, are not reported, unless the other institution is a consortium
 partner of the Center as established by previous CCSG peer review.
- Report only the cancer-related funding for all projects. For projects that are not entirely cancer related, report only the cancer-related portion of the funding, as estimated by the Center. These estimates should be defensible in peer-review.
- For projects that are on a no-cost extension, list the unobligated balance in the Annual Project and Annual Program Costs.
- For projects in which a portion of the award is subcontracted to other institutions, report the full amount of the award in Project Costs, but only the portion of funding retained at the Center in Program Costs.
- Provide subtotals of the Direct and Total Costs at the bottom of each of the 4 tables.
- Consortium Centers: Submit one DT 2A and 2B for the entire consortium.

Provide the following information:

PI: The last name and first initial of the PI from your Center 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: Use the application or grant number. This unique identification number for NIH grants, for example, is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code (e.g., 1R01CA059736-01).

Project Start Date: Official date a grant award begins; same as the first day of the first budget period.

Project End Date: Official date a grant award ends; same as the last day of the final budget period.

Project Title: The official title of the research project being carried out (e.g., Regulation of mitochondrial inheritance in yeast); please be as complete as possible

Annual Project Direct Costs: Annual funding awarded for a particular project

Annual Project Total Costs: The total annual direct and indirect (facilities and administrative) costs awarded to the Center to carry out a project

Program Code: Provide the code of the Program, as defined by the Center in DT 1B, with which this grant is associated. A single grant or contract may be associated with multiple programs

Percent: The portion of the funding associated with a Program

Annual Program Direct Costs: The portion of direct cost funding associated with the indicated Program

Annual Program Total Costs: The portion of the total costs associated with the indicated Program

The following examples are illustrated in the table:

Note: Do not number the rows – that is for illustration purposes in this example table.

- 1. One PI, one program. This grant is 100% associated with Program 4.
- 2. One PI, two programs. If the PI has dual membership in multiple programs, or if for other reasons the grant/contract should be associated with more than one program, divide the Annual Project Costs between the programs in proportion to the Percent. For the second program, you may leave all fields blank except the Program Code, Percent, and Annual Program Costs.
- 3. Multi-PI, one program. List all PI names. If there are more than three, you may use "et al." The NIH definition of multiple PIs may be used for grants/contracts from all funding sources:

- "Multiple PIs have equal authority for the grant or contract and are jointly responsible for the scientific and technical direction of the project" (http://grants.nih.gov/grants/multi_pi/faq.htm#a1).
- 4. Multi-PI, two programs. List the PI names twice (or more, depending on how many programs the grant is associated with), leaving the other fields blank except Program Code, Percent, and Annual Program Costs associated with each Program.
- 5. Multi-PI with one PI being at another institution. List the other institution after PI name. If the grant flows to the Center and a portion goes to the other institution as a subcontract, report the total funding in Annual Project Costs and list the portion that remains with the Center in Annual Program Costs.
- 6. Subcontract from another institution. List subcontracting institution after Specific Funding Source. List only the funds flowing to your Center under Annual Project Costs and Annual Program Costs.
- 7. Grant with portion subcontracted to another institution. List total funding to Center in Annual Costs; list only the retained portion in Program Costs.
- 8. National trial authored by a Center member; list only the funding that remains with the Center in both Project and Program Costs.
- 9. Multiple project/component grant (such as SPORE or P01). List overall PI with the Annual Costs, leaving Program Costs blank. List subprojects separately with overall PI name and subproject PI name. Note: as for all grants, use code ZY for any funding that is not a research project (e.g., cores, instrumentation grants, CCSG), and/or does not fit into a research program (grants to non-aligned members).
- 10. For accrual-based trials, list the funding awarded for actual or estimated number of patients enrolled in the reporting year.

| <u>Ex.</u> | PI | Specific Funding Source | Project Number | Project Start Date | Project End Date | Project Title | Annual Project Direct Costs | Annual Project Total Costs | Prog Code | Percent | Annual Program Direct Costs | Annual Program Total Costs |
|------------|----------------------------------|-------------------------------|------------------|--------------------------|---------------------|---|--------------------------------------|-------------------------------------|--------------|---------|--------------------------------------|-------------------------------------|
| 1 | Alfred L | NCI | 1R01CA059736-01 | 6/1/2014 | 5/30/2019 | Triterpenoids as chemopreventive agents | \$200,000 | \$300,000 | 4 | 100 | \$200,000 | \$300,000 |
| 2 | Dubois Y | NCI | 5R01CA067893-02 | 9/1/2012 | 8/30/2017 | Star trial (Tamoxifen vs. Raloxifene) | \$100,000 | \$150,000 | 1 | 60 | \$60,000 | \$90,000 |
| 2 | | | | | | | | | 5 | 40 | \$40,000 | \$60,000 |
| 3 | Birmann B Glick D | NINDS | 1R01NS046045-03 | 3/1/2013 | 2/28/2018 | Targeting the anti-apoptotic protein survivin in glioma | \$140,000 | \$210,000 | СВ | 100 | \$140,000 | \$210,000 |
| 4 | Bhorjee J Vembu D | NHLBI | 1R01HL056899-01 | 5/1/2015 | 4/30/2020 | Natural ligands of the aryl hydrocarbon receptor | \$200,000 | \$300,000 | МСВ | 100 | \$110,000 | \$165,000 |
| 4 | Bhorjee J Vembu D | | | | | | | | ET | 100 | \$90,000 | \$135,000 |
| 5 | Michaels H Herman B (UCSF) | NCI | 2R01CA876-098-02 | 12/1/2013 | 11/30/2018 | Southern Community Cohort | \$300,000 | \$450,000 | Epi | 100 | \$250,000 | \$325,000 |
| 6 | Donegan A | NHLBI Dartmouth | 3R01HL08685-03S2 | 8/1/2012 | 7/30/2017 | Calpain and p120 catenin regulation of cadherin function | \$50,000 | \$75,000 | 3 | 100 | \$50,000 | \$75,000 |
| 7 | Wang T | NCI | 3R01CA07196-03 | 8/1/2012 | 7/30/2017 | Southern Community Cohort Study | \$275,000 | \$412,500 | 3 | 100 | \$220,000 | \$330,000 |
| 8 | 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 |
| 9 | Lee R | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer | \$1,000,000 | \$1,300,000 | | | | |
| 9 | Lee R | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer Project 1: Anti- tumor Mechanisms of SRC Inhibitors in Lung Cancer | | | 2 | 100 | \$250,000 | \$375,000 |
| 9 | 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 | \$60,000 |

| 9 | Lee R Jackson A | NCI | 5P40CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer: Core A: Tissue Procurement, Pathology, and Bioinformatics | | | ZY | 100 | \$250,000 | \$375,000 |
|----|--------------------------------|-------|-----------------|----------|------------|---|-----------|-----------|----|-----|-----------|-----------|
| 9 | Lee R Sherman W, Smith E | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer Project. 2: E2F's Impact on Therapeutic Efficacy | | | 1 | 100 | \$220,000 | \$330,000 |
| 9 | Lee R Stuart, J | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer: Project. 3: RRM1 in the Management of Lung Cancer | | | 1 | 100 | \$240,000 | \$360,000 |
| 10 | 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 |

An example of a complete DT 2A follows:

2P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY Data Table 2A – Active Funded Projects

PEER-REVIEWED RESEARCH PROJECTS

| PI | Specific Funding Source | Project Number | Project Start Date | Project End Date | Project Title | Annual Project Direct Cost | Annual Project Total Costs | Prog Code | Percent | Annual Program Direct Costs | Annual Program Total Costs |
|----------------------|-----------------------------------|-------------------------|--------------------------|------------------------|---|-------------------------------------|-------------------------------------|--------------|---------|--------------------------------------|-------------------------------------|
| Alfred L | NCI | 1R01CA059736- 01 | 6/1/2010 | 5/30/2015 | Regulation of mitochondrial inheritance in yeast | \$200,000 | \$300,000 | 4 | 100 | \$200,000 | \$300,000 |
| 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 |
| Bariick A Glick D | NINDS | 3R01NS046045-03 | 3/1/2012 | 2/28/2017 | Targeting the anti-apoptotic protein bcl-2 in glioma | \$140,000 | \$182,000 | 3 | 20 | \$140,000 | \$182,000 |
| 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 | \$135,000 | 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 | \$50,000 | \$65,000 |
| 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 |
| | | | | | | | | 5 | 40 | \$40,000 | \$52,000 |

| | | | Peer-Reviewe Subtot | | | \$8,697,000 | \$11,771,000 | | | \$7,861,800 | \$10,707,840 |
|-------------------------------|-----------------------|-----------------------|------------------------|------------|---|-------------|--------------|----|-----|-------------|--------------|
| Smith K | NCI | 5P30CA010518- 42S1 | 4/1/2011 | 3/31/2016 | Consolidated Basic Cancer Research Program: CURE Supplement | \$120,000 | \$180,000 | ZY | 100 | \$120,000 | \$180,000 |
| Smith K | NCI | 5P30CA010518-42 | 4/1/2011 | 3/31/2016 | Consolidated Basic Cancer Research Program | \$2,000,000 | 3,000,000 | ZY | 100 | \$2,000,000 | \$3,000,000 |
| Sir P John E | NSF | 1205439 | 5/1/2012 | 4/30/2015 | mHealth - Computing Infrastructure for Mobile Health and Wellness Monitoring | \$628,000 | \$817,000 | 1 | 10 | \$62,800 | \$81,640 |
| 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 | \$280,000 | 5 | 100 | \$215,000 | \$280,000 |
| Partridge 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 |
| Offens M News H | 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 |
| Murphy J | NCI | 3P30CA022354- 30S | 5/1/2013 | 4/30/2014 | Cancer Center Support Grant: Community Health Educator | \$140,000 | \$182,000 | ZY | 100 | \$140,000 | \$182,000 |
| Mellon C | NIDDK | 5R01DK053265-03 | 2/1/2013 | 1/31/2018 | In vivo Selection for Stem Cell Gene Therapy | \$600,000 | \$780,000 | 4 | 20 | \$520,000 | \$582,000 |
| Lee R Stuart J | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancern Proj 3: RRM1 in the Management of Lung Cancer | | | 1 | 100 | \$225,000 | \$292,500 |
| Lee R Sherman W Smith W | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer Proj 2: E2F's Impact on Therapeutic Efficacy | | | 1 | 100 | \$110,000 | \$165,000 |
| 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 | \$277,500 |
| 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 | \$60,000 |
| Lee R | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer Proj. 1: Anti-tumor Mechanisms of SRC Inhibitors in Lung Cancer | | | 2 | 100 | \$250,000 | \$375,000 |
| Lee R | NCI | 5P50CA119997-04 | 3/1/2012 | 2/28/2017 | SPORE in Lung Cancer | \$1,000,000 | \$1,300,000 | | | | |
| 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 | \$40,000 | \$52,000 |
| 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 | 100 | \$600,000 | \$780,000 |
| Jacob M French A | 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 |
| 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 |
| 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 | 100 | \$80,000 | \$104,000 |

PEER-REVIEWED TRAINING PROJECTS

| PI | Specific Funding Source | Project Number | Project Start Date | Project End Date | Project Title | Annual Project Direct Cost | Annual Project Total Cost | Prog Code | Percent | Annual Program Direct 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 | \$36,000 | \$46,800 |
| Larson A | NHLBI | 5K08HL001711-04 | 2/1/2012 | 1/30/2015 | Serotonergic mechanisms is stress and anxiety | \$170,000 | \$221,000 | T | 20 | \$170,000 | \$221,000 |
| 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-Revie | ewed Training Subtotals: | | \$276,000 | \$358,800 | | | \$276,000 | \$358,800 |

NON-PEER-REVIEWED RESEARCH PROJECTS

| PI | Specific Funding Source | Project Number | Project Start Date | Project End Date | Project Title | Annual Project Direct Cost | Annual Project Total Costs | Prog Code | Percent | Annual Program Direct Costs | Annual Program Total Costs |
|----------|-----------------------------------|-------------------|-----------------------|------------------------------|---|-------------------------------------|----------------------------------|--------------|---------|--------------------------------------|----------------------------------|
| Miller L | Breast Cancer Research. 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 | \$1,530,000 |
| Norris C | AmItalian 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 |
| | | | | Peer-Reviewed rch Subtotals: | | \$1,440,000 | \$1,872,000 | | | \$1,431,000 | \$1,960,300 |

NON-PEER-REVIEWED TRAINING PROJECTS

| PI | Specific Funding Source | Project Number | Project Start Date | Project End Date | Project Title | Annual Project Direct Cost | Annual Project Total Costs | Prog Code | | Annual Program Direct Costs | Annual Program Total Costs |
|-----------|-------------------------------|----------------|--------------------------|---------------------|---|-------------------------------------|-------------------------------------|--------------|-----|--------------------------------------|----------------------------------|
| Dinh H | ASCO | CA5463545T | 9/1/2011 | 8/31/2013 | Enhancing Donor Cell Engraftment with CXCR4 Antagonist | \$100,000 | 130,000 | Т | 90 | \$90,000 | 117,000 |
| Roberts E | Prostate Society | T7564 | 3/1/2012 | 02/30/15 | Calibration and evaluation of a gene expression signature predictive of dasatinib sensitivity | \$23,000 | 29,900 | Т | 100 | \$23,000 | 29,900 |
| Smith L | Bayer HealthCare | 564CAA | 7/1/2013 | 6/30/2015 | Reproductive Scientist Career Development Program | \$75,000 | 97,500 | Т | 80 | \$60,000 | 78,000 |
| | | | Non-Peer-l Training S | | | \$198,000 | \$257,400 | | | \$173,000 | \$224,900 |
| | | | | | Grand Totals | \$11,111,000 | \$14,444,300 | | | \$9,025,800 | \$11,759,540 |

DT 2B

DT 2B describes the total number of cancer-related Research and Training projects and their aggregate total annual direct and total costs.

- For a center-defined reporting date, list the total number of cancer-related 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-review; and Industry Non Peer-Reviewed and Other Non-Peer Reviewed Projects.
- Provide subtotals and a grand total where indicated.
- For multiple project grants or contracts, count each subproject as one project (Do not count overall as one a SPORE with 5 subprojects would (example 9 above) would count as 5 projects.
- Follow the example below:

2P30CA120212-09

[Name of] Cancer Center Reporting Date: MM/DD/YYYY Data Table 2B – Active Funded Projects

| Specific Funding Source | Project Direct Cost | Project Total Costs | Total Number of Projects |
|---|------------------------|------------------------|--------------------------------|
| NCI Peer-Reviewed Projects | \$5,180,000 | \$6,734,000 | 13 |
| Other NIH Peer-Reviewed Projects | \$1,916,000 | \$2,490,800 | 9 |
| Other Peer-Reviewed Projects | \$2,377,000 | \$3,090,100 | 5 |
| Subtotal Of Peer Reviewed Projects | \$9,473,000 | \$12,314,900 | 27 |
| Industry Non-Peer-Reviewed Projects | \$325,000 | \$422,500 | 2 |
| Other Non-Peer-Reviewed 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 |

DT 3

DT 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, DT 3 therefore reports:

- 1) the number of newly registered patients at the Cancer Center (registry analytic and non-analytic cases, as defined below), and
- 2) the number of patients newly enrolled in interventional treatment trials (excluding consented but not enrolled patients, as defined below). In general, the source of newly registered patients and newly enrolled patients should be from the same populations (see table below). As this is intended as an overview, anatomic sites have been grouped for ease of review.

Note: Accrual data in DTs 3 and 4 do not correlate exactly and should not be directly compared.

Use the following definitions to complete the DT 3 table:

- Name of Reporting Source: For consortium centers or those with 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. 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-defined analytic case codes 00 22 http://www.facs.org/cancer/coc/fords/FORDS for 2011 01012011.pdf (pages 91 and 92);
 - 2) have recurrent or persistent disease and are referred to the Cancer Center for evaluation and treatment, *i.e.*, equivalent to American College of Surgeons-defined non-analytic code 32 (do <u>not</u> include other non-analytic codes).

Do not include:

- Any patient more than once unless they have two malignancies in the same year
- Consults (*e.g.*, second opinions), new patient appointments, diagnoses at autopsy, admission of former patients for rehabilitation purposes or treatment of some other condition, or patient follow-up after treatment

- Patients whose only contact with the Center is due to enrollment on protocol studies organized among community practitioners by Cancer Center staff
- Patients seen at Center clinical space but who are not eligible for the Center's clinical trials for non-scientific reasons (ineligible health plan, etc.), regardless of registry

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.

Follow this table to determine method of reporting Newly Registered Patients:

| Source of Patients | DT3 "Newly Registered Patients" |
|---|---------------------------------------|
| Cancer Center primary clinical arm(s), e.g., adult and pediatric hospitals and outpatient clinics that report through the Center's cancer | Include |
| Center primary clinical arm(s) that report through a separate cancer registry | Include as separate DT3 |
| CCSG peer-reviewed and approved consortium partner hospital or clinic that reports through the Center's registry | Include in same DT3 |
| CCSG peer-reviewed and approved consortium partner's hospital or clinic that reports patients through another registry | Include as separate DT3 |
| Cancer Center affiliates that do not report through the center's registry | Exclude |

Total patients newly enrolled in interventional treatment trials: Interventional treatment trials are protocols designed to evaluate one or more interventions for treating a disease, syndrome, or condition. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. **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.

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.

Example Format:

2P30CA120212-09

[Name of] 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 | 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 Intrathoracic 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 |

| Name of Reporting Source | | |
|--------------------------|------------------------------|--|
| Primary Site* | Newly Registered Patients | Patients newly enrolled in interventional treatment trials |
| Other Hematopoietic | 83 | 37 |
| Unknown Sites | 118 | 0 |
| Ill-Defined Sites | 3 | 13 |
| TOTAL: | 7945 | 924 |

DT 4

DT 4 serves as a report of the cancer-related hypothesis-driven clinical research studies open at the Cancer Center during a center-defined 12-month reporting period. Consortium centers submit only one DT4. Use the following definitions to complete DT 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:
 - o Studies of mechanisms of human disease
 - o Studies of therapies or interventions for disease
 - o Clinical trials, and
 - o 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.

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

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

Clinical Research Categories

Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, 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: Studies that focus on cancer patients and healthy populations and involve no prospective 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:

- o **Ancillary:** 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 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.
- o **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. Mapping of Previous and Newly Defined Clinical Research Categories

| Previous Clinical Research Category | Newly Defined Clinical Research Category |
|---|---|
| 1: Agent or Device | INTERVENTIONAL |
| 2: Trials Involving other Interventions | INTERVENTIONAL |
| 3: Epidemiologic or other Observational Studies | OBSERVATIONAL |
| 4: Ancillary or Correlative Studies | ANCILLARY/CORRELATIVE |

Study Source

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 organizations on this list: http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508 http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508 http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508

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:
 - o Institutional studies authored and implemented by investigators at another Center in which your Center is participating
 - Multi-Institutional studies authored and implemented by investigators at your Center (Note: National and externally peer-reviewed studies should be listed with those categories, not as Institutional studies)

Industrial: A pharmaceutical company controls the design and implementation of these clinical research studies.

Format

Sort the data by Clinical Research Category and Study Source:

INTERVENTIONAL National; INTERVENTIONAL Externally Peer-Reviewed; INTERVENTIONAL Institutional; INTERVENTIONAL Industrial; OBSERVATIONAL Externally Peer-Reviewed, etc., ANCILLARY/CORRELATIVE Externally Peer-Reviewed, etc.

Report the table alphabetically by PI.

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. Where available, list the NCT number, as well as the common protocol number that the trial is known under nationally, if one exists. For other trials that do not have an NCT number or a common

protocol number that the trial is known under nationally, use an internal protocol identification or IRB number.

PI: The last name and first initial of the PI from the Center who is responsible for this Clinical Research Study.

Program (Prog) Code: Use the Research Program code defined by the center in DT 1B. For clinical research studies that span more than one Research Program, include both Program Codes in this column.

Date Opened (activation): The official start date of a trial determined by 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.

Date Closed: The date the clinical research study closed to accrual. This does not include patient follow-up. 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."

Primary Purpose

- **Basic Science (BAS):** Protocol designed to examine the basic mechanisms of action (*e.g.*, physiology, biomechanics) of an intervention.
- **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.
- **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.
- **Treatment (TRE):** Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. **Note**: This equates to therapeutic trials in previous versions of the guidelines.

Other (OTH): Not in other categories

Table 4-2. Mapping of Previous Study Type and New Primary Purpose Designations

| 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) |
| Epi/Obs/Out | ОТН |
| Anc | OTH or BAS (depending on the nature of the study) |
| Cor | BAS |
| (No existing comparable Study Type) | HSR |

Note: Assign the appropriate Primary Purpose to Interventional or Non-Interventional (Observational or Ancillary/Correlative) Clinical Research Categories

Official Title: Official name of the protocol provided by the study PI or sponsor (Limit: 8000 characters or fewer).

Multi-institutional Clinical Research Study: Indicate if the trial is multi-institutional by inserting 'Yes' in the "Multi-inst study" column (see definition above).

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

Targeted Accrual for your Center: For single-institution and multi-institutional trials initiated at your Center, indicate the total number of participants your Center is expected to accrue for the study. For single-institution 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."

Accrual Institutions:

- Cancer Center: List the number of participants enrolled in the clinical research study at your Cancer Center, including formal Consortium Partners.
- Other Institutions: 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-institution trials led by your Cancer Center).

Accrual Timeframes:

- 12 Months: Provide the number of participants accrued to this clinical research study during the center-defined 12-month reporting period.
- To Date: Provide the number of participants accrued to this clinical research study since the trial was opened.

Notes:

- 1. For trials initiated and accruing patients only at your Center, the number of patients in the "Entire Study" and "Your Center" columns of the Total Targeted Accrual column should match. Enter the actual number of accruals in the "Cancer Center:" columns. Leave the "Other Accrual Institutions" columns blank.
- 2. For trials initiated and accruing patients at both your Center and additional Institutions, all columns under the "Total Targeted Accrual", "Cancer Center: Primary Accrual Institution", and "Other Accrual Institutions" should be filled in.
- 3. For trials your Center accrues to but did not initiate, leave "Entire Study" blank. Enter the Total Targeted Accrual for your part of the study. Enter the actual number of accruals under "Cancer Center:" Leave "Other Accrual Institutions" blank.
- 4. If the data are not available or applicable, leave the column empty.

The following examples illustrate how to report DT 4 data:

Interventional:

| | IN | INSTITUTIONAL | | | | | | | | | | | | Total Targeted Accrual | | Cancer Center Primary Accrual Institution | | ccrual ion(s) |
|---|-------------|----------------------------|---------------------|-------------|--------|--------------|----------------|----------------|-------|--------------------|---|--------------------------|-----------------|---------------------------|-----------|---|-----------|------------------|
| E | <u>x.</u> S | Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst study? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| 1 | , | NYU | Multiple | NCT002135 | Hook S | 10 | 8/15/2013 | | II | SUP | Etanercept in Patients With Idiopathic Pneumonia Syndrome After Undergoing a Donor SCT | No | 105 | 105 | 10 | 30 | | |
| 2 | ! | СОН, NСІ | Multiple | NCT204326 | Mack F | ET | 4/21/2012 | | Ш | TRE | Induction & Consolidation Chemo + Midostaurin v Placebo in Newly Diagnosed FLT3 Mutated AML | Yes | 400 | 60 | 22 | 46 | 70 | 240 |
| 3 | , | NCI | Myeloid leukemia | NCT 0046572 | Lehr D | 4 | 5/1/2012 | | Ι | TRE | Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia | Yes | | 6 | 0 | 4 | | |

Examples

- 1. A clinical research study that is initiated by your Center and carried out solely at the Center and its consortium partners
- 2. A study that is initiated at your Center and is carried out at your Center and other institutions.
- 3. A study that is initiated by another institution and in which your Center participates.

An example of a complete DT 4 follows:

DT 4 Example Format 2P30CA120212-09

[Name of] 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 Institution | | Other Accrual Institution(s) | |
|-------------------------------|---------------------|----------------|-------------|--------------|----------------|----------------|-------|--------------------|---|--------------------------|---------------------------|----------------|---|------------|---------------------------------|---------|
| Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst study? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| NRG | Bladder | NCT7785 23 | Armstrong C | 2 | 8/15/2013 | | III | TRE | Randomized chemo/rt/surg for bladder cancer | Yes | | 220 | 82 | 120 | | |
| Alliance | Myeloid leukemia | NCT 452761 | 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 | NCT6658 83 | Lehr D | 4 | 5/1/2012 | | I | TRE | Tamibarotene and Arsenic Trioxide for Relapsed Acute Promyelocytic Leukemia | Yes | | 6 | 0 | 4 | | |

| EXTERNALL | Y PEER-RE | VIEWED | | | | | | | | | | argeted crual | Cancer Center: Primary Accrual Institution | | Other A | |
|-------------------------------|------------------|--------------------------------|-----------------|--------------|----------------|----------------|-------|--------------------|---|--------------------------|-----------------|------------------|--|---------|--------------|------------|
| Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst study? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| NYU, NCI | Multiple | NCT 989551 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 | NCT4977 29 | Shepheard ,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 | | |

| INSTITUTI | ONAL | | | | | | | | | | Total Targeted Accrual | | Cancer Center: Primary Accrual Institution | | Other Accrual Institution(s) | |
|-------------------------------|------------------|--------------------------------|---------|--------------|----------------|----------------|-------|--------------------|--|--------------------------|---------------------------|----------------|--|------------|---------------------------------|------------|
| Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | | Multi- Inst trial? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| NYU | Breast | NCT990 0210NY U- 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 | NCT99 03451 | Bates S | 4 | 5/1/2012 | | I | TRE | Ofatumumab for indolent B-cell lymphomas | Yes | 10 | 6 | 0 | 4 | 2 | 4 |
| NYU | Multiple | NCT990 1201 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 | NCT575 757 | 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 | | |

| INDUSTRIA | IDUSTRIAL | | | | | | | | | | | | Cancer Center: Primary Accrual Institution | | Other Accrua | |
|-------------------------------|----------------------|----------------|--------|--------------|----------------|----------------|-------|--------------------|--|--------------------------|-----------------|----------------|--|------------|--------------|------------|
| Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | Official Tifle | Multi- Inst trial? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| GSK | Leukemia | NCT99035 41 | Day P | 10 | 3/1/201 | | I | SUP | Phase 1 Trial of Palifermin for Oral Mucositis | Yes | 15 | 15 | 6 | 8 | | |
| BMS | Lymphoid leukemia | DRUG 5013 | Head R | 8 | 5/1/201 4 | | III | TRE | Lenalidomide as Maintenance Therapy forPatients with B-cell CLL | Yes | | 113 | 47 | 79 | | |

Observational:

| EXTERNALI | LY PEER-RE | VIEWED | | | | | | | | | Total Ta Acci | | Cancer Primary Instit | | Other A Institut | |
|-------------------------------|--------------------------------|----------------|----------|--------------|----------|----------------|-------|--------------------|--|--------------------------|------------------|----------------|-----------------------------|------------|---------------------|------------|
| Specific Funding Source | Anatomic Site | Protocol ID | PI | Prog Code | | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst trial? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| NCI | Brain and Nervous System | NCT552 881 | Falls R | 8 | 7/2/2012 | | N/A | ОТН | Neurocognitiveoutcomes in pediatric brain tumor survivors following proton beam XRT vs conventional XRT | No | 100 | 100 | 13 | 30 | | |
| American Cancer Society | Prostate | NCT889 111 | Rogers S | 6 | 9/5/2014 | | N/A | ОТН | Focus group evaluation of prostate cancer symptom management education materials | Yes | 30 | 14 | 6 | 8 | 7 | 14 |
| NCI | Ovarian | NCT7785 236 | Lemon J | 3 | 6/1/2013 | | N/A | ОТН | Exogenous hormone use and risk of ovarian cancer | No | | 50 | 12 | 49 | | |

| INSTITUTIO | ONAL | | | | | | | | | | | argeted rual | Cen Prin Acci | ter: nary rual ution | Other Ad Instituti | |
|-------------------------------|---------------------|----------------|---------|--------------|----------------|----------------|-------|--------------------|--|--------------------------|-----------------|-----------------|---------------------|-------------------------------|-----------------------|------------|
| Specific Funding Source | Anatomic Site | Protocol ID | ΡI | Prog Code | Date Opened | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst study? | Entire Study | | 12 Months | To Date | 12 Months | To Date |
| NYU | Multiple | NCT9981 12 | Berry J | 8 | 5/1/2015 | | N/A | ОТН | Risk factors for childhood cancer and hematological disorders by case- control studies | Yes | 4000 | 1500 | 125 | 499 | 86 | 600 |
| NYU, NIH | Multiple Myeloma | NCT8891 11 | Smith S | 6 | 1/1/2010 | 4/7/2011 | N/A | ОТН | Treatment Decision Making in Older Adults Newly Diagnosed with MM | No | | 20 | 6 | 18 | | |

Ancillary or Correlative:

| INSTITUTIO | INSTITUTIONAL | | | | | | | | | Total Targeted Accrual | | Cancer Center: Primary Accrual Institution | | Other Accrua | | |
|-------------------------------|------------------|----------------|------------|--------------|-----------|----------------|-------|--------------------|--|---------------------------|-----------------|---|--------------|--------------|--------------|------------|
| Specific Funding Source | Anatomic Site | Proto ID | PI | Prog Code | | Date Closed | Phase | Primary Purpose | Official Title | Multi- Inst study? | Entire Study | Your Center | 12 Months | To Date | 12 Months | To Date |
| NYU | Brain | NCT99811 24 | Okra S | 8 | 2/23/2016 | | N/A | BAS | Phase I & 2 drug metabolism polymorphisms & outcome in children with medulloblastoma | No | 54 | 54 | 10 | 36 | | |
| NYU | Leukemia | NCT9909 91 | Granger I. | 8 | 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 | NCT87222 2 | Down R | 8 | 2/30/2014 | | III | ОТН | 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 | NCT778 851 | Gosden R. | 8 | 2/4/2015 | | N/A | BAS | Biology Study of Transient Myeloproliferative Disorder (TMD) in Children with Down Syndrome (DS) | No | | 17 | 1 | 3 | | | |
|-----|----------------------|---------------|-----------|---|----------|--|-----|-----|---|----|--|----|---|---|--|--|--|
|-----|----------------------|---------------|-----------|---|----------|--|-----|-----|---|----|--|----|---|---|--|--|--|

DT 5

DT 5 reports the Cancer Center's current budget (Type 2) and its requested budget (Types 1 and 2).

- Provide the direct cost CCSG budget of the last full year of funding (for Type 2), and the requested budget for the first year of the new competitive project period (Types 1 and 2) for each major budget category listed below. List non-salary funds for Research Programs separately, and list the shared resources individually. List only the total for Developmental Funds. Sum all the direct costs at the bottom of the chart.
- The current budget, if applicable, 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.

2P30CA120212-09

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

| CCSG Budget Category | Current Budget (direct costs)* MM/DD/YY – MM/DD/YY (Last full year of the current project period) | Requested Budget (direct costs) MM/DD/YY – MM/DD/YY (First full year of the new 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 | |
|--------------------|--|
| | |

^{*}DT 5 includes third party indirect costs. It does not include CCSG carryover funds or CCSG supplement dollars.

Summary of Changes to the Data Guide

| Updated Date | DT | Change |
|---------------------|--------------|---|
| 02/04/2015 | Overall | Simplified language; brought Data Guide and FAQs into agreement |
| | Introduction | Added table of describing appropriate DT submission |
| | DT 1 | Simplified column headings; removed embedded symbols from examples |
| | DT 2A | Simplified examples table; eliminated need to use embedded symbols to denote multi-PI projects or subcontracts; eliminated need to repeat some column data in reporting multi-program and multi-PI projects; examples and FAQ instructions brought into agreement |
| | DT 3 | Clarified definition of newly registered patients; added table describing the appropriate way to report data from consortium partners and affiliates |
| | DT 4 | Simplified column headings; inclusion of NCT numbers |
| 03/12/2015 | DT4 | To harmonize with CTRP, any Primary Purpose may be assigned to interventional and non-interventional studies (Table 4.3 therefore deleted). |