# Summary of Changes to the 2013 CCSG Data Guide

## General Changes

1. The document's name has been changed from Formatting for Standard Cancer Center Summaries to CCSG Data Guide. Individual summaries are now referred to as data tables.

2. A Table of Contents and an Introduction containing a Purpose Statement, General Instructions, and References have been added. You can now go to a specific section by clicking on its title in the Table of Contents.

3. There is greater emphasis on standardization of terms, and consistency and clarity in data submissions.

## Data Table 1

1. 1D: Marker for developing Shared Resource (SR) have been changed from (DEV) to an asterisk.

2. 1D: Some category codes for SR have been deleted:

    a. 2.04 Illustration/ Photography/ Typeset

    b. 4.02 Clinical Trials Protocol Management and Data Management

    c. 5.01 Secretarial/ Word Processing

    d. Category 5: Administrative

3. A column for identifying new leaders for programs and shared resources has been added.

4. A column for identifying new developing shared resources has been added.

## Data Tables 2A and 2B

1. Definitions for all components in the Data Table 2A table have been added.

2. Instructions for grants/contracts on No Cost Extension have been added.

3. Consortium centers are instructed to submit one Data Table 2A and 2B for entire consortium.

4. Nine separate examples have been added to illustrate how to list most types of research project grants and contracts.

5. Data Table 2B has been abbreviated, with some categories consolidated.

## Data Table 3

1. "Newly registered patients" definition is refined to highlight analytic and non-analytic cases as defined by specific ACoS Class of Case tables and a link to the codes has been provided.

2. "Treatment trial" has been changed to "Interventional treatment trial" for harmonization with other NIH mechanisms. A note has been added to clarify that this equates to "therapeutic trials" in previous guidelines.

3. Consortium centers and centers with affiliated institutions are instructed to include data only from those that are *formal* components of the center, not loosely affiliated community partners.

## Data Table 4

1. Several definitions have been added or modified:

    a. "Clinical Research" (NIH)

    b. "Epidemiological and behavioral studies" (2010 guidelines)

    c. "Health Services Research" (CTRP)

    d. Clinical Research Categories (CTRP)

    e. "Multi-site"

    f. "Accrual"

2. Consortium centers are instructed to submit one Data Table 4

3. A map comparing previous to new Clinical Research Categories has been provided.

4. The sort header "Trial Sponsor" has been changed to "Study Source".

5. Study Source should be listed for each Clinical Research Category, including Observational and Ancillary/Correlative studies.

6. The column header "Group/ Sponsor/ Funding Source" has been changed to "Specific Funding Source".

7. The definition of institutional trials has been expanded to include institutional studies authored by investigators at other institutions in which your center is participating.

8. *, **, and # are no longer used to denote various types of trials.

9. Some definitions have been harmonized with CTRP, such as “Date Opened” .

10. Phase 0 trials have been explicitly included

11. Primary Purpose definitions have been harmonized with CTRP.

12. A map of previous to new Study Type designations (Primary Purpose) is provided.

13. Instructions for Total Targeted Accrual have been modified.

14. A column has been added to indicate whether a study is multi-site under the CCSG Data Guide definition.

15. Three examples are provided to illustrate how differently administered clinical research studies are listed.

## Data Table 5

1. The Clinical Protocol and Data Management component has been added to budget lines.

2. Data Table 5 is now requested for new, as well as recompeting centers.