Office of Cancer Centers

Summary of 2013 Guidelines Changes

Component	Changes
<u>Director's Overview and Six Essential Characteristics</u> ***(Section 2.6)***	***Note: Page Limits for these sections and the Director's Overview have been changed to comply with NIH requirements.***
• ***Director's Overview (12 pages)***	Page limit change only
• ***Organizational Capabilities (12 pages)***	<u>Additions</u> Integration of education and training of biomedical researchers and health care professionals, including those from underserved populations, into programmatic research efforts Focus on cancer research in the catchment area <u>Deletions</u> Overlap with requirements of Planning and Evaluation Component Data on non-aligned members <u>Clarifications</u> Centers may vary in the nature and range of training and education activities they sponsor
• ***Transdisciplinary Collaboration and Coordination (12 pages)***	<u>Additions</u> Movement of findings through the translational pipeline via coordination with NCI and other peer-reviewed funding mechanisms Interactive activities beyond grants and publications are acceptable Encouragement of collaborative links with other centers, institutions, industry

• ***Institutional Commitment (12 pages)***	Additions Recognition of team science in promotion and tenure policies
• ***Center Director (6 pages)***	Additions Management and use of authorities and resources to advance the center's research mission Deletions Overlap with institutional commitment re director's authorities
• ***Facilities (6 pages)***	Page limit change only
• ***Cancer Focus (6 pages)***	Page limit change only
Consortia ***(Section 1.7)***	Additions Ongoing, tangible commitments from all consortium partners to the cancer center Examples of acceptable forms of 'tangible' support Deletions Requirement that all clinical trials must be open and available in all partner institutions Clarifications Requirement for each consortium partner to hold a portfolio of peer-reviewed cancer related grants Requirement that consortium operate as one cohesive center at time of application Role of the grantee and consortium partners in joint planning and evaluation processes

Senior Leadership ***(Section 2.7.1)***	Additions Expanded role for senior leadership in establishing a vision, fostering basic discovery and appropriate translation, enabling a focus on cancer research in the catchment area, and establishing a process for integrating training and education into programmatic research Examples of how the center might document senior leadership involvement in integration of training Guidelines relevant to enabling a research focus in the catchment area are cross-referenced to examples in section 2.8.5, Research Programs.
Developmental Funds ***(Section 2.7.4)***	Additions Opportunities to share meritorious resources across centers, fund staff investigators (including a new category focused on special populations research), and support global health pilot projects Leadership and participation in clinical trials as evidence of success for new recruits Clarifications Developmental funds are restricted
Administration ***(Section 2.7.5)***	Additions Focus on oversight of activities relevant to the CCSG application process Clarifications Administrative functions and subsequent applicability of review criteria may vary, based on organization's structure
Clinical Protocol and Data Management ***(Section 2.10)***	Additions Broader range of functions eligible for CCSG support, including those focused on speeding the clinical trials process, reporting for CTRP New Review criteria added for CPDM Instructions for DSM plans and budgets Modifications Table on accrual to interventional trials shortened and clarified, based on Data Table 4 Review criteria for DSM shortened

Research Programs ***(Section 2.8)***	***Note: Each program is now limited to 12 pages of narrative, per NIH requirements.*** ***A list of exclusions to these page limits is provided in the guidelines.*** Additions Opportunity to request program development funds in addition to salary support For basic science, specific language recognizing non-translational endpoints For clinical/translational programs, focus on quality of trials, coordination across NCI mechanisms, movement of findings through the translational pipeline, participation/leadership in NCTN, institutional trials that capitalize on center research Focus on how the center addresses cancer research in its catchment area, with examples Broader range of activities to document collaboration Value added by shared resources Stronger language on participation of clinical investigators in program Definition of 'cancer health disparities' Instructions on handling PMCID numbers in the application Deletions Requirements for agendas, data on non-aligned members, benchmarks for collaborative publications and clinical trial accrual Modifications Listing only of those publications making scientific impact/impact for patients/ demonstrating collaborative activity within and outside the center Review criteria that address accrual issues for trials of rare cancers and targeted therapies Requirement for at least 5 peer-reviewed and funded research projects in a Program Clarifications Definition of 'cancer-related' Crediting of collaborative publications across multiple programs

Shared Resources	Additions More emphasis on support of science as opposed to usage metrics Language on institutional resources and those supported by other NIH mechanisms Purchase of small equipment Deletions Usage and capacity tables Clinical Protocol and Data Management as a shared resource
Protocol Review and Monitoring System	Additions Encouragement of 2 stage review (concept then full protocol) Request for information on how the center assesses efficiency of functions, greater emphasis on documentation of process Simplified reporting templates One time opportunity for re-evaluation during the project period in cases of conditional- or dis- approval Text on special considerations for accrual to trials involving rare cancers and targeted therapies, along with link to policy/list of rare cancers Clarifications Full scientific review should focus on institutional and industry trials Processes for re-evaluation in cases of conditional- or dis-approval Procedures for review of institutional trials from other centers
Early Phase Clinical Research Support (formerly Protocol Specific Research Support) ***(Section 2.12)***	Additions Expands use of funds to early phase clinical research activities , e.g., imaging scans, pharmacodynamic studies and support for IDE or IND applications Requests for information on studies to be supported and outcomes of former studies

Inclusion of Women and Minorities ***(Section 2.13)***	Additions All centers provide plans for recruitment and retention of women and minorities Accrual of women and minorities to non-interventional studies, per NIH policy Optional inclusion of information on other underserved populations
Comprehensiveness ***(Section 2.18)***	Modifications A 1-stage review focusing on quality and interactivity of science as before, effectiveness of the center in serving its catchment area through the research it supports, and how the scientific mission of the center is enhanced by integration of training and education into programmatic research efforts.
P30 Funding ***(Sections 1.8, 2.2)***	Additions New budget guidance for Type 2 applications, establishing caps at various levels based on current year direct cost award Deletions Elimination of Benchmark Ratio Modifications Eligibility requirement for application raised to $10 M Clarifications Funding policies and factors influencing award levels
Review Process ***(Sections 3.2.2, 2.22)***	Addition Application only option, with new eligibility criteria and review process Deletions Limited site visit option Scoring for 'Overall Quality of the Programs' Some materials formerly made available at the site visit, shared resource logs Modifications Posters optional, but updated information may be provided in the slide book

Supportive Data/ Data Tables (formerly Standard Cancer Center Summary Information/Summaries)	***Note: To comply with NIH requirements, the names of the tables have been changed. Additionally, in the instructions for application, the Supportive Data is embedded in a "Resources Section" to assure conformity with PHS 398 approved components.*** For other changes, consult "Summary of Changes in the 2013 CCSG Data Guide"
Other/Overall	Additions Clicking on a section heading or table name in the Table of Contents will take you to that section in the document Clicking on a footnote or section number will take you to that footnote or section Links to the PHS 398 website for forms and instructions Glossary of Acronyms A footnote to additional guidance on defining 'catchment area' in multiple components of the document Request for LOI, 6 months in advance of submission Modifications Integrated instructions to applicants and review criteria in text Review criteria presented as questions 'Competitive Revision Applications changed to 'Revisions', per NIH requirements 'Administrative Revision Applications' changed to Administrative Supplements', per NIH requirements 'Percent effort' changed to 'person months', per NIH requirements Principal Investigator (PI) changed to Project Director/Principal Investigator (PD/PI) per NIH requirements Deletions $500K/1M letter of agreement to accept the application