TEMPLATE AND INSTRUCTIONS FOR CLINICAL PROTOCOL AND DATA MANAGEMENT

CCSG 2015

Specific Aims (1 page)

Summarize the broad, long-range objectives and goals of the Clinical Protocol and Data Management Core.

[continued below]

Research Strategy (12 pages)

Include the following 4 parts

Part I: Clinical Protocol and Data Management (formerly a shared resource)

It provides central management and oversight functions for coordinating, facilitating, and reporting on the cancer clinical trials of the institution(s) that define the center, whatever the study origin (local, industrial, NCI National Clinical Trials Network, or other). As a tool for management of a center's clinical research enterprise, it complements the Protocol Review and Monitoring System. It also provides a central location for cancer protocols, a centralized database of protocol-specific data, an updated list of currently active protocols for use by center investigators, and status reports of protocols. Quality control functions might include centralized education and training services for data managers and nurses; data auditing for tracking of patient accrual, assessment of patient eligibility and evaluability, timely submission of study data, and other study compliance measures; and data and safety monitoring activities that ensure the safety of study participants.

Briefly discuss the role of the CPDM in relation to management and coordination of the cancer clinical trials of the center, ensuring timely completion and initiation of trials, and conducting effective quality control and training functions.

Part II: Data and Safety Monitoring

DSM is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk.

The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring" NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

DSM functions are distinct and should not be the direct responsibility of the Protocol Review and Monitoring System (PRMS), which oversees scientific aspects of cancer clinical trials. Do not merge these activities and committees.

Provide a very brief summary of the Center's DSM plan. Do not include the entire plan within the text but provide a copy as per Section V.2 (Review and Selection Process/ Review Materials to be Available) of this FOA.

If funding is requested, include a description of: the DSM workload relevant to investigator-initiated studies and studies supported on competitive grants, including evaluation, auditing, and monitoring of patient safety based on phase, level of risk, or other pertinent factors. Do not include DSM activities directly supported on other grants and contracts.

Note: Review of the DSM plan by peers is an NIH requirement, separate from, and unrelated to, the separate review and approval of the plan by NCI program staff.

Part III: Inclusion of Women and Minorities:

It is the policy of the NIH (NIH Revitalization Act of 1993-Section 492B of Public Law 103-43) that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of

Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02- 001.html); a complete copy of the updated Guidelines is available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

When women or minorities are substantially under-represented in relation to catchment area demographics, the adequacy of the institution's policies, specific activities and a corrective plan become especially critical in convincing peer reviewers that the institution is serious about addressing the problem and is investing the appropriate effort to correct under-accrual. In addition, if the population of the catchment area of the cancer

center has limited ethnic diversity, provide a discussion of the institution's efforts to broaden the ethnic diversity of its clinical trial accrual.

In addition to the above, you may also include information in this section on other underserved populations (e.g., rural, elderly, low socioeconomic status) within the center's catchment area if desired.

Plans for Accrual of Women and Minorities: In this section, include a description of:

- Any general policies of the parent institution designed to help with recruitment and retention of women and minorities.
- Evidence or data that support unavoidable circumstances impeding accrual and retention of women and minorities (*e.g.*,
  a high proportion of non-eligible patients).
- Actions planned or being taken by the center, based on careful analyses of the catchment area, which demonstrate a
  clear effort to recruit and retain women and minorities and correct deficiencies that are potentially avoidable.

Part IV: Inclusion of Children in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

[continued below]

Project Summary/Abstract (30 lines)

[continued below]

Attachments

Attachment 1: *Overview of accrual to interventional clinical trials over the project period preceding the renewal application. [Note: this is a summary of Data Table 4 interventional trial data and the definitions, reporting years, and accrual sites used in Data Table 4 apply to the data in this table]*

Centers may also provide data on accrual to non-interventional clinical studies in a similar format if desired, using Data Table 4 for observational, ancillary, and correlative studies.

[Admin team to provide data]

Reporting Year (specify mm/yyyy)				
National Group				
External Peer Review				
Institutional (investigator initiated)				
Industry				
Total Accrual to Interventional Clinical Protocols				

Attachment 2: *For the Inclusion of Women and Minorities, include in tables information on: Demographics. In three sections, provide summary information showing the demographics of the primary geographic catchment area of the Center by ethnic categories and subcategories and by gender, as well as for the cancer patient population treated at the Cancer Center. Centers have the option of also providing data on demographics of cancer patients in the catchment area, if available.*

[Admin team to provide data]