

## FAQs related to the CCSG Guidelines

### **1. Will each scientific program be required to support cancer research relevant to its catchment area?**

Not all programs are expected to address cancer research relevant to the center's catchment area. However, as appropriate to the type of Program, research relevant to the catchment should be addressed (e.g., problems affecting racial and ethnic minorities, rural residents, women, children, elderly, persons of low socioeconomic status, cancer sites of high incidence/mortality, environmental exposures, behavioral factors, or other issues).

### **2. How will comprehensiveness be measured in future reviews?**

Comprehensiveness will be evaluated based on the following:

- How adequate are the depth and breadth of science in each of the three major areas of basic laboratory, clinical, and prevention, control and population sciences?
- What is the degree of evidence for strong transdisciplinary research bridging these sciences?
- How effectively has the center defined the cancer problems relevant to its catchment area and served its catchment area, as well as the broader population, via the research it supports?
- How is the scientific mission of the cancer center enabled by training and education of biomedical scientists and health care professionals?

Centers will no longer demonstrate community outreach and service in the CCSG application and evaluation. It is assumed that such activities will be required in order to effectively engage in research addressing cancer research problems in the center's catchment area.

### **3. What defines a consortium partner?**

Each partner in a consortium cancer center must contribute a peer-reviewed research portfolio that significantly expands or strengthens the center's research programs. A consortium partner must be a fully integrated and functioning part of the cancer center at the time of review – not sometime in the future. Finally, a formal, written agreement between the partnering institutions must be in place to ensure stability and integration of the consortium.

**4. What is a cancer health disparity?**

The [National Cancer Institute](#) defines a [cancer](#) health disparity as an adverse difference in cancer [incidence](#) (new cases), cancer prevalence (all existing cases), cancer death ([mortality](#)), cancer [survivorship](#), and burden of cancer or related health conditions that exist among specific population groups in the United States.

**5. How will reviewers evaluate accrual to clinical research studies of rare tumors?**

It is noted in the 2013 CCSG guidelines that clinical research studies of rare tumors may have relatively small or slow accrual. This includes studies of rare molecular subtypes of more common cancers. CCSG reviewers should make allowances for this. A link is provided in the guidelines.

**6. How is accrual defined?**

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

**7. What is an institutional clinical research study?**

A clinical research study may be considered institutional if:

- The study is authored or co-authored by Cancer Center investigators and undergoes scientific peer-review by the PRMS of the center
- The study is one in which your center is participating but was authored by investigators at other institutions or centers and reviewed by that center's PRMS

**8. Is it permissible to request a Staff Investigator as TBN?**

No. The credentials of a Staff Investigator will continue to be an important review criterion and therefore a specific candidate must be proposed. However, if a change in Staff Investigator during the grant cycle is necessary, the NCI will consider the request. The center should contact its CCSG program director.

**9. What review criteria will be used to evaluate a Center's decision to use Developmental Funds to purchase shared resource services at other NCI-designated Cancer Centers?**

Review criteria are the same for all categories of developmental fund use, i.e., how effectively the center has used developmental funds to strengthen cancer-related science; how effective the center has been in using internal and external advisory bodies to assist in identifying scientific opportunities and needs; and how appropriate plans are for future use.

**10. How will collaboration with other NCI-designated Centers be reported?**

Collaboration with other research institutions, including NCI-designated Centers, should be documented in Research Programs, Senior Leadership, and Organizational Capabilities sections. As part of Transdisciplinary Collaboration and Coordination, the Center should report how it has moved findings through the translational and clinical continuum by partnering with other research institutions and NCI-designated Cancer Centers. Metrics could include publications, clinical research studies, and grants shared by investigators at multiple Centers, but the primary focus is on how collaborations enhance the Center's science, not numbers.

**11. How will education and training of biomedical researchers be addressed in the application?**

The education and training of biomedical researchers will be a review criterion in two CCSG components: Organizational Capabilities and Senior Leadership. Emphasis should be directed towards how education and training are integrated into programmatic research efforts to enable the scientific goals of the Center. Examples include: appointment of an Associate Director or center wide committee to focus on coordination, integration, and monitoring of education and training efforts; regularly scheduled meetings or retreats focused on training; formalized mentoring or career development programs; tracking of training outcomes for junior investigators; development of approaches for recruitment of trainees from underserved populations; and other activities. The range and nature of activities may vary based on type of center.

**Note** that education and training is not a specific review criterion for the Research Programs and need not be addressed in the Programs sections.

**12. What constitutes an important scientific contribution of a program?**

It is not possible to create strict review criteria to quantify the importance of scientific contributions. This will continue to be, as it has been in the past, in the eye of the review team.

**13. Does NCI define “membership” in a Cancer Center program?**

Centers define membership for themselves. However, once defined, the Center should adhere to its own membership criteria.

**14. Will Shared Resource posters be expected to detail usage and capacity?**

Detailed usage and capacity tables are no longer required for either the application or for posters (which are optional). The application should include the following data on use of services: total number of users, total number and percent of users who are center members with peer-reviewed support, and total number and percent of users who are center members without peer-reviewed support. This information may be updated in the slide book at the time of the site visit, if desired.

**15. What does NCI mean by”...enabling a focus on cancer research in the catchment area?”**

In addition to questions of broader applicability, and as appropriate to the type of Program, the Center should describe how the cancer research relevant to the catchment area is addressed. This does not mean that Centers should study only cancer research important to their catchment area, just that they should not ignore such areas of research while they pursue cancer research questions of national and international importance.

**16. Can Centers apply to be “exceptions” for the 10% limit on budget requests?**

The guidelines state that: "Larger budget increases (*greater than 10% over the previous budget*) should be requested only under exceptional circumstances." The only exceptional circumstances the NCI will currently consider are the first re-competing application after a no-cost extension or after an award reduced by 50% or more following the previous review. The Office of Cancer Centers should be consulted before such a request is made.

**17. What is the timeline for implementation of the new guidelines and Data Tables?**

Although the 2013 guidelines were just released, they are in effect for all Centers, including those that competed under the 2010 guidelines. Guidance for preparing

the Type 5 (non-competing) application has been posted on the OCC website. Please consult your OCC Program Director for further instructions.

### FAQs related to CCSG Review

**18. Is the 5-hour time limit for the site visit negotiable? Should we plan for breakfast and lunch? Are they included in the 5-hour time limit?**

The CCSG Guidelines state “Site visits usually extend a maximum of 5 hours at the center...” A decision on the exact time limit for the site visit will be made in consultation with the Scientific Review Officer (SRO). As before, centers should plan on breakfast and for a mid-day Executive Session (which includes a brief working lunch for the site visit team); the Executive Session/Lunch is included in the 5-hour time maximum frame. Breakfast is not included in the 5-hour time maximum frame.

**19. Considering the new 5-hour time limit, can the center choose to not present some components?**

Ultimately, it is the center’s choice as to what components will be presented at the site visit, but exclusion of critical components, such as the CPDM, PRMS, accrual of minorities/women/children, and the six essential characteristics should be carefully weighed. **All** components included in the CCSG applications, even if not presented by an applicant during the site visit, require a question/answer period (up to a maximum of 10 minutes) at the site visit.

**20. What is the purpose of the shared resource groupings? How do you suggest they be grouped?**

The purpose is to align the shared resources (by groups) with the science the shared resources support in the Research Programs. In the new version of the CCSG Guidelines, the focus is on the importance of the shared resources to the science of the center. Each Program should address the value of applicable shared resources to its research, i.e., the contribution made by the shared resources to programmatic science. Each shared resource should address how it supports the science of the center’s Programs.

Shared resources should be grouped into 3 categories with this in mind. Unique shared resources may be placed in an ‘other’ category, for a total of 4 categories. How the shared resources are grouped is entirely up to the Center. A Center may have less than 4 groups, if that allows the best alignment with programmatic research.

These changes will allow the review committee more time to devote to review of the center's science.

**21. Will there still be tours?**

There will be a tour of the clinical trials office and reviewers may request other tours.

**22. How is one merit descriptor determined for several separate shared resources?**

Shared resources will be discussed and voted on by group, not individually. The review will be based on the review criteria in the CCSG Guidelines, using the full range of merit descriptors available. A group of shared resources may receive one merit descriptor (*e.g.*, excellent) or a range (*e.g.*, excellent to very good). Voting per group of shared resources will not be based on an average of what would have been the individual shared resource scores (merit), and there is no predetermined ranking of shared resources value in a group; rather, merit will be determined by the relative value of the shared resource group in supporting the Center's science.

**23. Do we submit one narrative and budget for each shared resource, or for each group of shared resources?**

Each shared resource should have a separate narrative and budget, as before. Centers may renegotiate with OGA following the award to decide the final budget of each shared resource.

**24. How will reviewers be trained in the new guidelines? What happens if reviewers insist on using the old metrics? Will the SRO and/or Program intervene?**

Reviewers, including both standing members of IRG-A (the parent committee) and *ad hoc* site visit team members, will be instructed in the new guidelines and review criteria by the Scientific Review Officer. Both the SRO and Program Director will monitor adherence, as in the past.

**25. Since the Clinical Protocol and Data Management component is no longer a shared resource, how should it be presented and how will review change?**

The CPDM is presented as a separate component in the application and at the site visit. This allows specific review criteria to be established, and they are:

- How effective is CPDM in centralizing, managing, and reporting on the cancer clinical trials of the center?
- To what extent does CPDM help to assure timely initiation and completion of clinical trial activities?

- How effective are the quality control functions and training services offered by the CPDM?
- How reasonable is overall accrual, based on the nature/type of the individual trials supported?

**26. How will a shared resource serving multiple centers be evaluated?**

The evaluation of shared resources that serve multiple centers will not differ. The emphasis will continue to how that SR advances the programmatic research efforts of the Center where it resides. Scientific collaborations with other institutions that utilize a shared resource should be discussed in the narrative.

**27. How should training and other efforts conducted in conjunction with the Clinical and Translational Science Award (CTSA) be presented?**

To the extent that these efforts further the scientific goals of the center, or enhance its capabilities, they should be presented.

**28. How can shared resources be shared between institutions?**

Shared resources may be shared within an institution that is the home of the cancer center; for example, a shared resource may be supported and serve both the cancer center and the CTSA. A shared resource may also be shared with other institutions, through the use of developmental funds used to purchase services at other NCI-designated centers.

**29. For programs, how extensive and what kind of information about collaborations should be presented?**

Each research program narrative is limited to 12 pages; the list of intra- and inter-programmatic activities and external collaborations is an exclusion from the 12-page limit. In the narrative you should present only the most important scientific collaborations, those that advance the scientific goals of the Research Program, and you should present enough information to document the importance of the collaboration.