FAQs related to the CCSG Applications

1. **What does NCI mean by"… cancer research relevant to the catchment area?"**

   In addition to questions of broader applicability, and as appropriate to the type of Program, the Center should describe how it carries out cancer research relevant to its catchment area. This refers to more than accrual to the center's clinical trials. Cancer research that addresses the catchment area could include research projects that address: 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.

   This does not mean that Centers should study only cancer research important to their catchment area, but that Centers should include such research in their larger portfolio of cancer research addressing questions of national and international importance. NCI has no metric as to how much of a Research Program's research should address the catchment area, but it is expected that most cancer research is relevant to a broader population than exists in any center's catchment area.

   In addition to the Research Programs, cancer research relevant to the catchment area should also be discussed in Senior Leadership and Organizational Capabilities.

2. **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. Basic research programs have not generally been expected by reviewers to carry out catchment area-relevant research, although if a basic program does so, it's certainly a strength that should be described in the application and site visit. However, reviewers have generally expected to see research relevant to the catchment area in the population science programs and programs that have a substantial clinical trials effort.

3. **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 be required to demonstrate community outreach and service in the CCSG application and evaluation; however, such activities will be necessary in order to effectively engage in research addressing cancer research problems in the center's catchment area.

4. 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.

5. 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.

6. How will reviewers evaluate accrual to clinical research studies of rare cancers?

It is noted in the FOA that clinical research studies of rare cancers 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 FOA in the PRMS component.

7. How is accrual defined?

Accrual is based on 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.

8. 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

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

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

The FOA states 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 a 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. If a center permits an investigator to hold membership in multiple programs, how should the center treat the member's publications and grants?

The publications and grants of an investigator with multiple program memberships may be allocated to each program as appropriate/relevant to the research of that program. The center should be prepared to justify their inclusion in each program (i.e., relevance to programmatic aims or other research in the program; reviewers should examine the relevance of the research to the program's stated goals and, ultimately, the productivity of that research). Thus, a single publication or grant may be discussed in the write-up of different programs. However, care should be taken to ensure that reviewers don't feel that the same research effort (publication or grant) is being "counted" twice in reporting total number of publications and grants or overall center productivity.

If an investigator with multiple program memberships splits a grant between programs, the grant may be counted in both programs with regard to the research program minimum of 5 peer-review projects.

18. How does the NIH Public Access Policy affect CCSG competing applications?

NIH requires PMCIDs for publications directly supported by NIH mechanisms. For CCSG applications, these are publications that result from: pilot projects supported by Developmental Funds, clinical studies supported by Early Phase Clinical Research Support, and projects which received subsidies/discounts for the purchase of Shared Resources. PMCIDs do not have to be listed in CCSG applications for papers supported by other NIH mechanisms.

Centers should provide separate lists of publications with and without PMCIDs in the Research Program Narratives.

19. How are training grants reported?

In Data Table 2, all training grants should be listed separately from Research Projects, broken out into Peer-Reviewed and Non-Peer Reviewed tables, using the program code "T". Training grants are not listed in the Research Programs nor should the funds be counted in the Research Program total.

20. Should the calculation of requested budgets be based on the noncompeting pre- or post-sequestration award figure?

Until further notice, Centers submitting competing applications should base their requested budget on their last pre-sequestration award figure, which occurred in FY12.

FAQs related to CCSG Review

21. How much time is devoted to the site visit?

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.

22. Can the center choose to not present some components?

Presentations are required for some critical components, such as the CPDM, PRMS, accrual of minorities, women, and children, and the six essential characteristics. For other components, it is the center's choice as to what will be presented at the site visit. All components included in the CCSG applications, even if not presented by an

applicant during the site visit, require a single question/answer period (up to a maximum of 10 minutes) at the site visit.

23. What is the purpose of the shared resource groupings? How does this affect the review?

Groupings allow the site visit team to streamline the review of the shared resources and devote more time to the review of the center's science. Centers should align the shared resources with the science the shared resources support in the Research Programs. The focus of review will be 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 can be grouped in up to 3 categories with this in mind. Unique shared resources may be place in an "other" category, for a total of 4 categories. A Center may have less than 4 groups, if that allows the best alignment with programmatic research. How the shared resources are grouped is entirely up to the Center and is not a review criterion.

The review of the shared resource groups will occur on the night before the site visit and will be based solely on the written application. If the reviewers gather fresh information at the site visit, they may choose to reopen the discussion of the shared resource group(s) and revote.

24. 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 FOA, 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 outstanding). 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.

25. What about posters or videos on the shared resources?

Poster sessions are not required, although they do serve as a focal point for reviewers to talk to the shared resource leaders. As an alternative, a center could include updated information in the slide book presented to the reviewers. However, it is still a good idea to have the shared resource leaders available to the review team following the executive session.

The purpose of the site visit is gather information updated since the written application was submitted. Videos describing the shared resources, while not prohibited, have not proven to be a valuable way to convey updated information.

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 program narratives.

27. 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. The centers will receive one budget per group of shared resources, and will with OGA following the award to decide the final budget of each shared resource.

28. 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 program narratives.

29. 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.

30. Will there still be tours?

The tour of the Clinical Trials Office is still expected, but if geography prevents quick access to the CTO, the Center may opt to stage the visit in a room with access to all protocol material (either hard copies or digital form) the review team may want to examine and with all personnel they may want to question. This should be discussed with the SRO prior to the site visit.

Rarely, review teams may request a visit to a specific shared resource, if they have questions that are relevant to review.

31. One criterion for review of Shared Resources is "…how effective are accessibility policies governing institutional and other specialized shared resources." What does this mean?

Critical core services, whether they are supported by the CCSG or by institutional or other funds, should be readily accessible to all center members on a timely basis. If reviewers doubt the ability of members to access core services, it could negatively affect the review of that core.

32. 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?

33. 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 it capabilities, they should be presented.

34. 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.

35. What format and time period should the center use in reporting intra- and inter-programmatic publications, external collaborations, meetings, seminars, etc.?

The center may choose the format, but the lists should cover the most significant contributions/events of the preceding grant cycle (usually 5 years).

36. Are consortium centers expected to discuss consortium characteristics in each program?

No, the consortium arrangements should be discussed only in those programs where relevant – when there is a significant contribution of the consortium to the program's scientific efforts. Inter-programmatic collaborations should cross the spectrum of the center's programs, including those with consortium partners in other programs, however.

37. What trials should be included in the Protocol Review and Monitoring section of the application? What if a trial has been approved by the PRMC but is not yet activated, and thus is not listed on Data Table 4?

In the PRMS section of the application you are asked to list, in Data Table 4 format, all institutional trails (i.e., studies that have not received external review) that were reviewed by the PRMC during the reporting year. You should have different columns indicating studies that were approved and activated, approved but not yet activated, deferred for revision, disapproved, or closed (you may use a coding system as described in the FOA).

38. When the Protocol Review and Monitoring System receives conditional approval or disapproval, how does the Cancer Center know what issues to address and how soon the re-review occurs?

In cases of conditional approval or disapproval of the PRMS, the peer reviewers will clarify in the Summary Statement what steps or changes are needed for full approval, along with any recommendations on timing of re-evaluation by peers.

Following the final summary statement, the OCC will contact the center and describe the re-review procedure.