

Frequently Asked Questions (FAQs) Related to the Cancer Center Support Grant (CCSG)

1. What if a Center has a Research Program that does not meet the minimum number of peer- review cancer-relevant grants?

The OCC recommends, as would any responsible EAB, that Centers present to reviewers stronger, better funded Research Programs, even if that means fewer Programs. Therefore, the NOFO sets a minimum number of investigators and peer-review projects that Research Programs should possess at the time of CCSG submission. Failure of a Research Program to have the minimum funding set forth in the NOFO may adversely affect the impact score.

2. How is the term “R01-equivalent” applied?

R01-equivalence is defined as a grant of \$125,000 per year for 3 years. This term only applies to achieving the minimum number of funded projects in a Program (and to qualify as a consortium partner). Grants from NIH and the other peer-review funding organizations recognized by NCI count towards the minimum

3. Does the term “R01-equivalent” mean the Center can’t count any grant less than that?

Once a Research Program achieves the minimum number of projects, the term “R01-equivalent” is irrelevant, and all peer-reviewed research projects are included as specified in the Data Guide. For example, if a Center member’s only funding is a subcontract for \$80,000 from another center, that member is a peer-reviewed funded investigator, that is a research project listed in the relevant Program, and that funding is listed in DT2A and rolled into the total in DT2B.

4. What defines a consortium partner?

A consortium partner with clinical activities is defined in the CCSG as an institution that:

- holds a portfolio of at least \$2.5 million in direct cost NIH-funded research project grants that are classified as cancer research by NIH’s Research, Condition, and Disease Categorization (RCDC), held by a minimum of 10 PD/PIs.
- provides continuing tangible commitments to the center.
- is fully integrated the level of membership and institutional engagement into the cancer center at the time of application.
- subjects all clinical protocols to the Cancer Center’s Protocol Review and Monitoring System (PRMS), Data and Safety Monitoring Institutional Plan (DSMP), and Clinical Protocol and Data Management (CPDM).
- has participation of the partner’s members in Center’s disease or modality-focused groups, PRMS, and DSMP.
- grants the Cancer Center Director some influence in the management of the clinical cancer care program at the consortium partner to ensure that care is aligned with the research mission of the Center.
- has appropriate accrual to clinical trials proportionate to the patient population and

- clinical research capabilities of the consortium partner.
- has an appropriate cancer research administrative structure and staff to support cancer research, member engagement, and participation in Center activities, and that coordinates its efforts with the Center's administration.
- has a formal, written agreement (Memorandum of Understanding) in place to ensure the stability and integration of the consortium partnership.

A consortium partner without clinical activities must satisfy the requirements listed above, not including clinic-related activities, and hold at least \$1.0 million in direct cost NIH-funded research project grants that are classified as cancer research by NIH's Research, Condition, and Disease Categorization (RCDC), held by a minimum of 5 PD/Pis.

5. How are consortium arrangements reviewed?

Reviewers will rate each arrangement "Satisfactory/Unsatisfactory" based on the above requirements. This occurs as "Additional Review Considerations," meaning it takes place after all other components are evaluated. NCI will then approve or disapprove the consortium when issuing the Notice of Award.

6. What if a newly proposed or existing consortium arrangement does not meet these standards?

Each consortium partner, whether newly proposed or established, is evaluated with each Center's application. Although the "Additional Review Considerations" under which the consortium arrangement is reviewed takes place after all other components are scored, and does not carry an impact score itself, proposal of an inappropriate consortium arrangement may affect the overall impact score of the center if reviewers' question CCSG components such as Leadership, Planning and Evaluation, and Organization Capabilities.

Institutions that do not meet the minimum portfolio or other requirements may be considered affiliated organizations. Investigators at affiliated institutions can enjoy all the benefits of membership in the cancer center, including access to shared resources, CCSG funding for pilot projects, salary, etc. Peer-reviewed grants from these PIs cannot be counted in the center's funding base, and their institution cannot use the NCI- designation in its branding.

7. 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 that exists in any center's catchment area.

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

Reviewers expect to see cancer research relevant to the catchment area addressed in each program, at a level appropriate to the type of program (basic, clinical, translational, and population science).

9. 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.

10. 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.

11. 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.

Although not specifically called for in the NOFO, one way for Centers to demonstrate external collaborations is to calculate the total percentage of publications achieved through inter-institutional collaborations, either Center-wide or within Research Programs

12. How should a center assess cancer relevance?

Each center can choose its own method of assessing the cancer relevance of non-NCI grants. It should be justifiable to reviewers. We recommend centers have a rigorous process that they present to reviewers at the site visit.

FAQs related to the Site Visit

Site visits are currently being held in a virtual format. The following FAQs are related to in-person site visits.

1. 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.

2. 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.

3. What about posters on the shared resources and tours of shared facilities and the Clinical Trials Office?

Shared Resources are no longer toured, although there is usually a Shared Resources poster session. While these poster sessions are not required, they do serve as a focal point for reviewers to talk to the shared resource leaders and are thus recommended.

Likewise, there are no tours of the Clinical Trials Office. There is, however, a session (held concurrently with the Shared Resources poster session) during which issues regarding Clinical Protocol & Data Management; the Protocol Review & Monitoring System; and Inclusions of Women, Minorities, and Individuals Across the Lifespan are discussed.

4. What about posters on other topics?

A Center may choose to have posters addressing other topics they wish to present to reviewers, although there is no guarantee that reviewers will visit them.