Frequently Asked Questions

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
- However, if a Center has a Research Program that it feels achieves significant scientific
 impact but does not meet the minimum, they are free to include it in their application.
 Reviewers are instructed that they are free to ignore the minimum if they determine
 that the Program has significant impact

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

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

What defines a consortium partner?

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

- holds a portfolio of peer-reviewed, cancer-relevant grants (at a minimum, 7 peer-reviewed, cancer relevant grants of \$125,000 per year for 3 years from at least 5 Pls)
- is fully integrated into the cancer center at the time of application
- provides continuing tangible commitments to the center
- is governed by a formal, written agreement

How are consortium arrangements reviewed?

• Reviewers will rate each arrangement "Acceptable/Unacceptable" based on the above requirements. This occurs as "Additional Review Criteria," meaning it takes place after

all other components are evaluated. NCI will then approve or disapprove the consortium when issuing the Notice of Award.

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 Criteria" 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-review grants from these PIs cannot be counted in the center's funding base, and their institution cannot use the NCI-designation in its branding.

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.

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.

What is a cancer health disparity?

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

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.

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 interprogrammatic 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 FOA, 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

How is a Center's budget eligibility calculated?

- The OCC will determine a Center's total budget eligibility based on NIH cancer-relevant funding for the previous fiscal year. For NIH funding other than NCI, the Research, Condition, and Disease Categorization system in RePORTER is used to determine cancer relevance. Funding from non-NIH sources are excluded from the calculation.
- At OCC's discretion, some mechanisms may be excluded from the calculation for a variety of reasons. For example, large infrastructure grants (such as the P30 itself and association supplements, data coordinating centers, etc.) will be excluded. Exceptionally large awards, if they significantly increase budget eligibility beyond what the Centers

Program can fund, may also be excluded. These decisions are carefully considered by OCC and will apply to all Centers.

Does the budget eligibility calculation affect what the center presents in the application?

 No, centers are free to include any grant they feel is cancer-relevant, as peer-reviewed (if from NIH or the approved peer-reviewed organizations) or non-peer-reviewed (not to be included in research programs. Reviewers are cautioned about conflating these two different lists.

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

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.

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.

What about poster 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 and are thus recommended.

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.

Will there still be tours?

- Tours of shared resources are no longer allowed.
- 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.