

Clarification on Policy for Review of Minority and Gender Representation in P30 Cancer Center Support Grant (CCSG) Applications

Background

Concerns about the review of minority and gender representation in P30 CCSG applications have been raised by Center Directors at the last several NCI Directors' Retreats. Specifically, they have questioned the appropriateness of basing approval of minority and gender representation on accrual to therapeutic trials alone, especially given the increasing focus of the NCI and NIH on prevention, early detection, and screening efforts. Although we have operated for a number of years under the assumption that the current approach was congressionally mandated, we initiated a review of the NIH Revitalization Act of 1993 (Sec 429B), NIH policy on gender and minority representation, and our CCSG Guidelines following the November, 2005 Directors' Retreat.

Conclusion

The current practice of basing approval/disapproval of minority and gender representation solely on accrual to therapeutic trials is not specifically mandated. A broader approach to assessment is consistent with policies and guidelines and should ultimately prove constructive in fostering overall scientific progress, increasing representation of women and minorities in clinical trials, and ensuring general applicability of trial results across underserved populations.

New Approach for Review

Applicants will submit separate tables for accrual to therapeutic and non-therapeutic interventional clinical trials as before. (Accrual to epidemiologic, outcome, observational and other non-interventional studies should not be included in these tables). Reviewers should assess the total picture, taking **both** therapeutic and non-therapeutic interventional clinical trial accrual into account in relation to approval/disapproval of gender and minority accrual, per the current review criteria in the CCSG Guidelines:

- Appropriateness of the accrual of women and minorities to therapeutic and non-therapeutic clinical trials in proportion the center's catchment area
- When accrual is inadequate, adequacy of center's plan to improve performance