Guidance Regarding the CCSG Clinical Support Element, Protocol-Specific Research Support (PSRS)

As a follow-up to our previous discussions on CCSG support for clinical support elements, further clarification of the Protocol-Specific Research Support (PSRS) element is provided below as questions/answers for two of the confusing areas: eligibility of studies supported by industry, eligibility of non-therapeutic studies, and behavioral studies.*

Q. Are early phase trials that receive partial support from industry also eligible for support from the PSRS?

A. Yes, so long as the trial is conceptualized and designed primarily by an institutional investigator and has been approved by the PRMS Committee. Trials designed solely by the industrial sponsor are NOT eligible for PSRS support.

Q. Are studies that do not involve the testing of new agents or devices (i.e., behavioral studies) eligible for PSRS support?

A. No, PSRS support is restricted to those early phase, proof of principle trials that involve testing of a new agent or device. If behavioral studies are proposed for support by an applicant, however, the peer review panel does have the option to evaluate the merit of these studies and include their recommendations in the review. If viewed as meritorious by the peers, program staff will negotiate a funding solution with the applicant administratively that does not involve the PSRS.

*This information does not in any way replace the information provided in the CCSG Guidelines; rather, it is meant to provide clarification.