Centralized Review Process Markedly Expedites Approval of Cancer Clinical Trials

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(PhysOrg.com) -- A Central Institutional Review Board (CIRB) for cancer clinical trials that was created by the National Cancer Institute (NCI), part of the National Institutes of Health, in 2001 helps trials start more quickly (just over a month faster, on average) and thus expedite the time from concept to completion of crucial investigational research according to a new finding. This study of the CIRB was performed by scientists at the Veterans Affairs Palo Alto Health Care System (VAPAHCS) and Stanford University School of Medicine, Palo Alto, Calif., with assistance from NCI and appears online October 19, 2009 in the *Journal of Clinical Oncology*.

Over the past 40 years, more than 1,700 institutions in the United States have enrolled up to 20,000 patients annually in phase III clinical trials coordinated by NCI and have used separate IRBs to monitor research involving patients. Federal regulations require that most NIH-funded clinical trials be monitored by an IRB.

To determine whether a new treatment is safe and more effective than current treatments using clinical trials is a lengthy process that can take up to 10 years and cost more than $1 billion, in some cases. Many researchers have complained that administrative requirements, including IRB oversight, are delaying the release of new treatments. One solution NCI proposed was to form a CIRB to conduct IRB review of large, multi-site oncology trials.

"Mounting a CIRB that is nationwide in scope has been challenging for

NCI due to the complexity involved in assuring high-quality protection for study participants while attempting to speed the process," said Jeffrey Abrams, M.D., associate director of NCI's Cancer Therapy Evaluation Program. "For all the volunteer reviewers and participating sites, this study provides objective confirmation that a centralized approach significantly improves the overall process for participants in multi-site trials."

The study assessed whether use of NCI's CIRB was associated with lower effort, time and cost in processing adult phase III oncology trials, which are the gold-standard of trials for validating whether a therapy becomes a new standard of care. Early phase trials (phase I and II) and pediatric trials were not included in the analysis due to the lower patient enrollment populations required.

Clinical trial sites that are not enrolled with the CIRB must have their local IRB conduct a full board review as they would with any research study. Sites enrolled with the CIRB have their local IRB conduct a facilitated review, which is a review category requiring only that the local IRB chairperson or designee signal acceptance of the CIRB's review.

To determine whether the CIRB was achieving the hoped-for efficiencies, researchers compared clinical trial review at sites affiliated with the NCI CIRB with the review at unaffiliated sites that used their local IRB. Oncology research staff and IRB staff were surveyed to understand differences in effort, timing and costs of clinical trial review. CIRB affiliation was associated with faster local review (about 34 days) and about six hours less research staff effort. Many clinical trials sponsors value faster and more predictable reviews and often pay commercial, fee- for-service, central IRBs to perform reviews.

Affiliation with NCI's CIRB was also associated with a savings of $717

per initial review, of which about half was associated with time savings for research staff and the remainder was associated with savings for the IRB staff. Overall, the program resulted in a net cost of $55,000 per month for NCI, but the CIRB could actually save costs if more sites were to use the CIRB. Moreover, this net cost estimate does not include the benefits of bringing new cancer therapeutics to market more quickly.

"Efforts are underway to expand enrollment in the CIRB and to encourage sites to use the CIRB to minimize administrative inefficiencies," said lead researcher Todd H. Wagner, Ph.D., health economist, VAPAHCS and Stanford University School of Medicine, Palo Alto, Calif., "and based on our research, increased efficiencies and net savings are likely."

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