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TO: Clinical Department Chairs

Clinical Department DFAs

FROM: Harry B. Greenberg, M.D., Senior Associate Dean for Research

Marcia Cohen, Senior Associate Dean for Finance and Administration

DATE: October 17, 2012

SUBJECT: Increasing the Clinical Trial Budget Development Fee

In September 2007 we instituted a Budget Development Fee of \$2,500 on all new industry-funded clinical trials. The fee was implemented as a result of increased administrative and procedural compliance requirements. These requirements include staff effort to conduct a coverage analysis, align the contract and budget with the protocol and consent, negotiate the budget with the sponsor, and coordinate the budget with the department staff, IRB, Spectrum OTC, Stanford Hospital and Clinics/Lucile Packard Children's Hospital.

Effective November 1, 2012, the Budget Development Fee will increase to \$3,200 for new studies. The increased fee will be budgeted and negotiated on new industry-funded clinical trial budgets prepared by either the Research Management Group or the Cancer Clinical Trials Office.

In addition, the RMG will implement a \$640 Budget Amendment Fee for sponsor amendments for budget revisions. The new amendment fee will be budgeted and negotiated for only new industry-funded clinical trials received in RMG starting November 1, 2012. Existing awarded studies will not be impacted. The CCTO already has an Amendment Fee that will remain at \$640.

Please note: these fees are only applicable to industry sponsored clinical trials and are not applicable to clinical trials supported by non-profit foundations, voluntary health organizations, and government sponsors.

Please feel free to contact your Clinical Trial RPM (http://med.stanford.edu/rmg/contact.html) if you have any questions about the fee.

cc: Kathleen Thompson, RMG Debbie Leong-Childs, RMG Miriam Bischoff, CCTO