STANFORD
SCHOOL OF MEDICINE
Stanford University Medical Center

Research Management Group
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TO: Sponsors Requesting Justification of IRB Fees

FROM: Debbie Leong-Childs
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DATE: April 3, 2012

SUBJECT: IRB Review fee for New and Continuing Review (Renewal) of Industry-funded Clinical Trials

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This is an update of the memo issued May 1, 2006 from Ann Arvin, Dean of Research and Harry Greenberg, Senior Associate Dean of Research, School of Medicine.

The Stanford University Office of Cost and Management Analysis (CMA) performed a cost-analysis of the IRB fee that is charged for the review of new industry-sponsored clinical trials, i. e., all studies which test an investigational drug or device on human subjects and are sponsored by private, for-profit entities. The University established the present fee of $2,000 ($2,560 including indirects) in 2001, after an extensive evaluation of the IRB costs at that time. In light of many new administrative and procedural requirements, authorized by the Office of Human Research Protections, the Food and Drug Administration, and the Association for the Accreditation of Human Research Protection Programs, CMA was asked to reassess the present fee.

Based on CMA's analysis of the IRB costs since 2001 and what other Universities and commercial IRBs are charging, the University implemented an IRB Continuing Review fee of $1,000 ($1,280 including indirect). This Continuing Review fee will apply to new industry-sponsored clinical trial proposals received by the Research Management Group (RMG), effective December 1, 2006. The Continuing Review fee will be collected annually at the time of the IRB Continuing Review. Relevant contracts already awarded or currently in process at RMG or Office of Sponsored Research will not be subject to an annual IRB Continuing Review fee. The resulting funds will be used to offset the cost of new IRBs, staffer IRB systems development and maintenance, new requirements from accrediting bodies, and other necessary changes as a result of increasing regulatory guidance.

As has been the case since the IRB fee was first introduced, non-profit foundations, voluntary health organizations, and government sponsors will continue to be exempt from the IRB fee. Also, if there is a compelling reason to sponsor cannot pay the IRB fee, waiver request can be filed. Please work with your Research Process Manager, should the situation arise.