

October 17, 2008

To: All Principal Investigators

From: Greg Kopf PhD
Associate Vice Chancellor for Research Administration

John Finley JD, MPH
Associate Vice Chancellor for Compliance

Re: Western IRB

In response to requests from investigators, the KUMC Human Research Protection Program has established a relationship with Western IRB. The resources of Western IRB will be available for investigators who are conducting Phase III or IV multi-center, industry-sponsored drug or biologic trials. The goal of our relationship with Western IRB is to provide more options for investigators and an enhanced ability to attract Phase III and IV studies to the institution. Western IRB is located in Olympia, Washington and is fully accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP). The use of Western IRB is not required; rather, it is an option that is available to KUMC investigators.

Submissions to the Western IRB (WIRB) must come from a designated liaison within the institution. The KUMC Research Institute (RI) will serve as the liaison on behalf of KUMC investigators. Submission of new protocols and regulatory documents by the RI will ensure that the RI is able to meet its contractual obligations with sponsors. The RI also will submit required documentation during the course of the study, including, but not limited to, protocol amendments, adverse event reports, and continuing reviews.

New protocols should be delivered to the RI as they have been in the past. The RI Clinical Research Administration division staff will coordinate the application process for using WIRB and assist the investigator in completing necessary regulatory documents, IRB forms and other documents needed for WIRB submission. If investigators request to use WIRB, a new form entitled "Request to Use Western IRB" must be completed and submitted to the RI along with all new study materials. The request form can found at:

<http://www2.kumc.edu/researchcompliance/hscwesternirb.html>

RI administrative fees will remain the same for IRB submissions regardless of which IRB an investigator chooses to utilize. The KUMC Human Research Protection Program will reduce their fee to \$500. There is a separate fee for the use of WIRB. The fee schedule for WIRB is attached for reference.

Please feel free to contact either Karen Blackwell (kblackwe@kumc.edu, X80942) or Diana Naser RN (dnaser@kumc.edu, X81242) should you have any questions.

Thank you for your attention.

Western Institutional Review Board® (WIRB)®

3535 Seventh Avenue, SW – P.O. Box 12029
 Olympia, Washington 98502
 1-360-252-2500

IRB FEE SCHEDULE (Payable in U.S. Dollars)

Effective April 1, 2008

*Amounts past due 60 days subject to 1% monthly interest
 (For locations outside the 50 United States, add 10% – For Canadian locations, add 10% plus GST)*

- Initial Review \$1,750.00
 Protocol/Grant
 Principal Investigator
 Consent Forms
 Recruitment Materials
- Multicenter Studies, Additional Investigators (each) \$ 825.00
 Site Specific Consent Forms
 Site Specific Recruitment Materials
- Study Renewal Review (each site, at least annually)..... \$ 825.00
- Changes to Research (each site)..... \$ 285.00
 Protocol Amendments/Revisions
 Consent Form Modifications
 New or Updated Recruitment/Retention Materials
 Change to Research Locations
 Increased Subject Enrollment Level
 Site Prepared Translations
 Other Changes to Research
- Co-Investigator or Change of Investigator..... \$ 825.00
- Videoconference..... \$ 350.00
- Teleconference..... \$ 150.00
- IRB Study Transfer..... \$ 550.00
For review of IRB and study records for research in progress, Initial Review fees also apply.
- Generic Non-Protocol Related Material..... \$ 550.00
*e.g.: Regulatory exempt determination, site pre-screening consent forms,
 generic advertising, centralized call screening or recruitment scripts*
- WIRB Translations Services..... Variable (*per English word*)
Minimum translator charge \$150 + Changes to Research Fee.
- WIRB Written Consent Form..... Variable (*\$150 per hour*)
Minimum charge \$450.

Protecting the Rights and Welfare of the Human Research Subject