

Submission Guidelines & Procedures to Western IRB for UMDNJ Investigators

- **Billing Procedure**

Effective April 1, 2007, there has been a change in the billing procedure for Western Institutional Review Board (WIRB) services. UMDNJ researchers submitting initial applications, continuing review applications and/or modifications of human subjects research to WIRB will indicate the name and address of the Sponsor in the “Billing Information” section of the WIRB submission form, in accordance with the Clinical Trial Agreement or study contract. This information will make clear to WIRB who will be responsible for paying the WIRB fees and whom WIRB should bill. The UMDNJ Human Subjects Protection Program (HSPP) will no longer be the payor of WIRB invoices nor the payee for sponsors to reimburse these fees. Sponsors will be billed by WIRB directly and will pay WIRB directly. There will also cease to be an administrative add-on fee in recognition of the reduced role of HSPP. Sponsors need only pay WIRB’s published fees (see below).

The applicable WIRB submission forms which request Billing Information are:

- Initial Review Submission Form (New Protocols)
- Investigator Submission Form for Multi-Center Protocols
- Change in Research/Subject Recruitment Submission Form
- Request for a Partial Waiver of Authorization for Recruitment (HIPAA Partial Waiver of Authorization)
- Request for a Waiver of Consent under the Common Rule and Waiver of Authorization under HIPAA (HIPAA Full Waiver of Authorization)
- Institutional Biosafety Committee Services (IBCS) Submission Form

New Clinical Trial Agreements and study contracts (CTAs) after April 1, 2007 will identify the Sponsor as the payor of WIRB invoices. UMDNJ’s attorney will ensure language is inserted into the CTA that clearly states the new WIRB billing procedures.

Effective April 1, 2007, the Western Institutional Review Board fees are as follows:

- Initial Review : 1,700
- Multicenter Studies: 800
- Continuing Review: 800
- Modifications: 275
- Co-Investigator or Change in Investigator: 800

- Videoconference: 350
- Teleconference: 150
- Generic Non-Protocol Related Material: 550
- WIRB Translation Services *Variable*
 - (per English word)
- WIRB Written Consent Form *Variable*
 - (\$150 per hour)