

Submission Guidelines & Procedures to Western IRB for UMDNJ Investigators

✚ Fee Schedule

UMDNJ Human Subjects Protection Program Submission Service Fee

Effective 2/1/09

One-time charge \$ 750

Western Institutional Review Board Fees

Effective June 1, 2009

Initial Review

- Initial Review of Protocol and Investigator \$1,750.00
Protocol/grant, principal investigator, first consent form, recruitment materials
- Additional Investigators, Multi-Center studies..... \$825.00
Per investigator. Includes previously approved consent form(s), site-specific recruitment materials. For multi-center studies with over 25 sites, please call for pricing.
- Additional Consent Forms (each) \$300.00

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Continuing Review

- Study Renewal Review (each site, at least annually)..... \$825.00
- Annual Review of Generic or Non-Protocol Related Material..... \$550.00

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Changes in Research

Protocol amendments/revisions, change to research locations, increased subject enrollment level, site prepared translations, new or updated recruitment/retention materials, other changes to research

- Changes to Research Involving Consent Form Review*..... \$350.00
- Changes to Research not Involving Consent Form Review* \$250.00
- Same Change, Each Additional Site..... \$150.00
- Co-Principal Investigator or Change of Investigator \$825.00

* Charges will be per submission unless the items require multiple and substantively independent review (e.g. consistent changes across several documents will receive a single charge; substantively different changes to different documents submitted at the same time but requiring independent review by the Board may receive more than one charge).

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Fee Schedule - Continued

Other Services

- Videoconference..... \$350.00
- Teleconference \$150.00
- Generic or 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
Cost based on number of words, minimum translation fee of \$150 plus \$300 administrative fee
- WIRB Written Consent Form..... Variable
\$250 per hour, minimum of 3 hours
- Consulting..... call for estimate
*IRB operations review
IRB audits
Protocol pre-review
Protocol writing
AAHRPP accreditation assistance
Development of SOPs
IRB regulatory support
Education,
Other services available*

Please contact WIRB for a detailed fee breakdown for your research, or for questions and additional fee schedules, including schedules for international and large multi-site trials.

All fees payable in U.S. Dollars

For locations outside the U.S. and Canada, please see International Fee Schedule.

For Canadian locations, add 10% plus GST

Amounts past due 90 days subject to 1% monthly interest

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Fee Schedule - Continued

IRB FEE SCHEDULE, Multicenter Studies

Effective June 1, 2009

Initial Review

• Initial Review of Protocol.....	\$925.00
<i>Protocol/grant, first sponsor consent form, recruitment materials</i>	
• Additional Sponsor Consent Forms (each).....	\$300.00
• Sites	
<i>Per investigator. Includes previously approved consent form(s), site-specific recruitment materials. Only sites using previously WIRB-approved consent form(s) are eligible for these prices. Charges below are per site.</i>	
Sites 1 through 25	\$825.00
Sites 26 through 50	\$750.00
Sites 51 through 100	\$600.00
Sites 101 through 200	\$500.00
Sites 201 and above.....	\$250.00

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Continuing Review

• Study Renewal Review (each site, at least annually).....	Variable
<i>Same as initial review charge for each site</i>	

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Changes in Research

Protocol amendments/revisions, change to research locations, increased subject enrollment level, site prepared translations, new or updated recruitment/retention materials, other changes to research

• Changes to Research Involving Consent Form Review	\$350.00
• Changes to Research not Involving Consent Form Review*	\$230.00
• Same Change, Each Additional Site.....	\$150.00
• Co-Principal Investigator or Change of Investigator	\$825.00

For other services, fees, and payment policies, please see WIRB's standard fee schedule

* Charges will be per submission unless the items require multiple and substantively independent review (e.g. consistent changes across several documents will receive a single charge; substantively different changes to different documents submitted at the same time but requiring independent review by the Board may receive more than one charge).