INITIAL REVIEW

- Initial Study Review $1,575
- Review of Principal Investigator (PI) $895/PI
  (including any subsequent replacement PIs)
- Each additional consent form $410

CONTINUING REVIEW

- Continuing Review of Study $950
- Continuing Review of Principal Investigator $785/PI

MODIFICATIONS AFTER INITIAL REVIEW

- Revised Informed Consent $290/PI
- Protocol Amendment (No Revision to Informed Consent) $290/PI
- Protocol Amendment (With Revision to the Informed Consent) $400/PI
- Review of Revised Product Information (i.e. Clinical Investigator Brochure) $290
- Recruitment/Retention Materials (Per Document) $210
  Processing Fee $90/PI
- Review of Other Supplemental Materials (Per Document) $210
  Processing Fee $90/PI
- Certified Translations Services (For All Submitted Translations) Cost Plus $150
  Translated Material Processing Fee $90/PI
- MA Regulatory-Required Site Visit $900
- Board-Directed Initial Compliance Assessment $900
- Review of HIPAA Waiver $90/PI
- Request for Study/Site Specific Acknowledgement $90

As an alternative to this fee-for-service schedule and item-by-item invoicing, the WIRB - Copernicus Group offers a simplified, cost-effective single-price option for any Study. Please call us if you wish to consider a single-price option.

INITIAL STUDY REVIEW INCLUDES THE FOLLOWING:

- Personalized and single WCG point of contact
- Experienced and knowledgeable board
- Review of protocol, clinical investigator brochure, study application form and one proposed informed consent form template
- Review of advertisements/supplemental materials including diaries, case reports, questionnaires and retention materials
- IND safety reports not included in current clinical investigator brochure
- Approved informed consent form template
- Approval letters detailing approved items with dates
- Quality checks at each step of process

REVIEW OF PRINCIPAL INVESTIGATOR INCLUDES THE FOLLOWING:

- Dedicated PI submission team
- Investigator site questionnaire review
- CV review
- 100% medical license verification
- Review of advertisements submitted with PI packets
- Site-specific customized informed consent form
- HIPAA waivers submitted with PI packet
- Detailed approval notice with expiration date
- Expedited review of qualifying PIs
- 24–48 hour turnaround time
- Quality checks at each step of process

TERMS: Net 30 days unless otherwise agreed to in writing. Late payments may be subject to a monthly finance charge of 1.5% of the amount owed from the due date until payment in full. WCG shall be entitled to recover all reasonable attorneys’ fees, costs and expenses associated with any efforts to recover payment for overdue invoices. Fees are subject to change without notice.