

Submission Guidelines & Procedures to Western IRB for UMDNJ Investigators

Billing Procedure

UMDNJ researchers submitting to WIRB initial applications, continuing review applications and/or modifications of human subjects research will indicate the name and address of the sponsor or the investigator 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. If the CTA or study contract indicates that the sponsor will reimburse the investigator for WIRB reviews, instead of the sponsor paying WIRB directly, write the name and address of the investigator in the “Billing Information” section of the WIRB submission form so that WIRB invoices will go to the correct place. The UMDNJ Human Subjects Protection Program (HSPP) does not pay WIRB fees. Sponsors or investigators will be billed by WIRB directly and will pay WIRB directly.

In addition to the WIRB invoice will be a one-time HSPP administrative submission service fee of \$750 for initial applications.. Sponsors will be billed separately by the HSPP staff. UMDNJ researchers submitting WIRB initial review application of human subjects research will indicate the contact information for billing the HSPP service fee in the “Billing Information” section of the *UMDNJ Application for Review by WIRB*.

New Clinical Trial Agreements (CTAs) and study contracts negotiated or signed after February 1, 2009 will identify the sponsor or the investigator as the payor of WIRB invoices. UMDNJ’s attorney will ensure language is inserted into the CTA that clearly states the WIRB billing procedures.

HSPP/WIRB Service Fees

Additional fees apply for the use of the WIRB review process.

The Human Subjects Protection Program (HSPP) will charge \$750 for each submission to WIRB. This fee includes:

- **Initial eligibility review**

HSPP staff will review each submission for assurance of proper training of all investigators, completeness of initial review documents, and eligibility for submission to WIRB in accordance with criteria agreed upon by WIRB and the University of Medicine and Dentistry of New Jersey (UMDNJ).

- **Initial submission to WIRB**

HSPP staff will submit all initial documents to WIRB for review. All further correspondence will take place between WIRB and the investigator.

- **Continuing local review of all protocols and study changes**

When a centralized IRB is listed as the IRB of record for a study, federal regulations require that the local IRB retain authority regarding local considerations, especially adverse events and unanticipated problems. Throughout the continuation of the study, the HSPP will review all decisions made by WIRB for such local considerations and may take additional action when necessary, including but not limited to expedited or full board review of unanticipated problems and adverse events, additions or changes to informed consent and assent documents, suspension pending inquiry, and even disapproval. A UMDNJ IRB cannot approve any protocol which has been disapproved by WIRB.

- **Record maintenance**

The HSPP will maintain all records of local review in accordance with applicable federal, state, and local law.