

AIDS Treatment News

ICC Trials -- Enrollment Problem

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The last issue of AIDS TREATMENT NEWS included information on enrolling in ICC 001, the first study of the Inter-Company Collaboration for AIDS Drug Development, a consortium of 15 major pharmaceutical companies. However, there is a potential problem in the enrollment process that we did not know about when that issue went to press.

Before patients will be screened for this trial, they must bring in blood work showing that they will probably pass the screening. According to the ICC protocol, this blood work must be within 30 days, and must include specified lymphocyte subsets, hematology testing, and serum chemistry. Since most people get their blood work done every three to six months, this can create scheduling problems. Check with the site about exactly what the requirements are.

\$150 per patient has been budgeted for miscellaneous expenses in the trial; sometimes it can be used if the patient's insurance will not cover the required tests.

Comment We have never heard of this pre-screening requirement before. It raises two concerns: (1) The 30-day limit will delay enrollment by up to several months, further slowing a study which has already had major delays.

(2) This is a new example of medical cost shifting. The usual result is to shift the burden of treatment and of research onto the party least able to pay -- the individual already facing the stress of major illness -- because the institutions which could easily pay can avoid the cost.

In this case, the additional cost of the usual flexibility -- taking whatever blood work is available, and accepting the risk of more unsuccessful screenings -- would probably average well under \$100 per patient, or well under \$22,500 for all the patients in the trial -- a small amount of money compared to the costs of doing clinical research.

[See the topic on aegis.org](http://aegis.org)