

All clinical trials are expected to pay a one-time fee of \$2,000 to the Office of Clinical Trials. Studies, which dispense drugs, are expected to use Investigational Drug Service, which charges a yearly fee ranging from \$500 to \$2,000 depending on whether the investigator initiated the trial and whether it is industry sponsored.

These fees must be included in the budget but are not subject to indirect rates. The sponsor is asked to pay these fees at the beginning of the project and an invoice for them is sent to the sponsor from the IRB or IDS office.

Frequently, however, the sponsor elects not to pay these by separate check but to include the fees in the first check to the PI. Instructions with the invoices request that they identify these payments but, in our experience, sponsors frequently do not do so.

If the fees are identified at the time the check is deposited, they are credited to the correct office; however, if they are not identified, OSR will assume that the entire check is for clinical trial expenses and will credit the trial. If, later, the IRB or IDS office has not been paid, they will send further invoices to the sponsor and/or PI. At this point, many PIs instruct their coordinators to pay these fees in the usual way, by using a check request. This method works, in the sense that the IRB or IDS is paid but money that is spent from a clinical trial account is subject to indirect costs. In other words, every time you pay an IRB fee by check request, you not only pay \$2,000 to the IRB but you also pay \$528 in indirect fees.

To avoid this, please follow these steps:

- When you get a sponsor check, especially if it is a first payment on a trial, review the check and any accompanying documentation to determine if it includes the IRB and/or IDS fee (or other funds that should not be deposited in the account).
- Fill out a Program in Digestive Health Accounting Route Sheet (yellow sheet) and on it list the IRB, IDS or other deductions to the deposit and bring the yellow sheet and the check to us.
- After the deposit has been made, check your account (or get one of the accountants to do so) and make sure the correct amount has been deposited.
- If, after the deposit has been made, you find that you (or OSR) have made an error or you get an invoice from IDS or IRB, bring this to the attention of the accounting staff immediately.
- The accounting staff will work with the affected offices to correct the problem.