CASE No. 4

This investigator is a clinical professor of medicine associated with a large medical school in the South. He had studied 45 investigational drugs for 21 sponsors.

Audit revealed:

1. Errors in reporting data to the sponsor.
2. Errors in recording laboratory findings.
3. Errors in selection of diseased patients for the study (patients who had recovered from the disease were used in the trials).
4. Inability to verify performance of laboratory tests claimed to have been made.

The investigator was declared ineligible. He instituted adequate record keeping facilities and improved supervisory practices, including overall supervision of the testing program by a peer group not otherwise associated with the clinical trials. He was reinstated as an investigator eligible to receive drugs for clinical trials.

CASE No. 5

This investigator is a medical and research director at a hospital in the South, primarily for retarded children. He had been named as investigator in 89 IND's and NDA's for 20 different drug companies.

Our investigation showed he had undertaken more investigational drug work than he could handle. Record-keeping was poor, patients were on concomitant investigational drug therapy, on investigational drug therapy, and therapy with multiple other unreported drugs.

There were irregularities in dates of drug administration and discrepancies in reported responses between hospital records and study reports. Patients were variously reported as male and female and three of these were males who were reported as having had "o.k. vaginas." Laboratory values in hospital records did not agree with those in case reports and there were examples of unsubmitted and undocumented laboratory data.

He was declared ineligible to receive investigational drugs.

The investigator completely revised his operating procedures. He employed a full-time medical consultant, appointed a research coordinator, established a peer research review committee to pass on protocols for future work and review on-going research, and he established adequate record-keeping procedures. He has been reinstated as eligible to receive investigational use drugs.

CASE No. 6

A physician at a hospital in the West was involved in 30 IND's or NDA's for 14 different drug companies.

We audited a study involving the administration of the drug to 103 hospitalized patients for periods approximating three months. Eighty-seven reports and charts were examined. In 71 instances, the dosage reported to the sponsor varied from that actually administered to the patient. In 62 instances, the duration of drug therapy reported to the firm was greater than that noted in the hospital chart, and in 34 of these cases, this discrepant interval exceeded 28 days.

In 39 cases, the diagnosis reported in the hospital chart differed from that reported to the sponsor. In 20 instances, the clinical courses reported to the sponsor and those noted in the hospital charts were at variance. Eighteen patients were found to have been discharged from the hospital on a date which significantly preceded the date of termination of the therapy reported to the firm. The NDA reports on these patients routinely noted laboratory work and/or clinical evaluations having been performed subsequent to the dates of discharge.

He has been declared ineligible to receive investigational drugs. He has not been reinstated.

CASE No. 7

An investigator in the West who was involved in 5 IND's submitted by four sponsors admitted that a report submitted on one study was completely false. She has been declared ineligible to receive investigational drugs and has not been reinstated.