

Unrelated Business Income Tax (“UBIT”)

Special Circumstances and Guidelines

14. Clinical Trials

- The IRS holds that “for benefit” drug testing is a related activity and therefore nontaxable, while “not for benefit” testing is unrelated activity which is subject to UBIT.

“For benefit” drug testing includes those studies in which drugs are offered to hospital patients who have the disease for which eventual commercial use of a particular drug is intended.

“Not for benefit” drug testing includes studies involving patients receiving care for unrelated medical reasons.

- Drug testing performed for commercial pharmaceutical firms merely to meet FDA requirements before marketing of the drug is taxable. The IRS held that this kind of testing is merely a service for the manufacturer rather than for public safety.
- Clinical testing for developmental equipment is also taxable. The IRS determined that even the experiments conducted using the instrument were clearly related to the university’s research purpose, the primary purpose of the research was the development and perfection of an instrument for marketing.
- Non-patient lab testing involving student training is nontaxable, given that the testing services contributed importantly and substantially to the medical education program.
- Production testing by students is nontaxable given that the contribution to the university’s educational purpose was more than incidental.
- Lab testing serving the community need is not taxable. If the testing facilities are otherwise unavailable in the community for a particular type of test, then the testing would service as an important community need, therefore service the University’s exempt purpose.