

## **INCENTIVES PAID BY SPONSORS OF MCO CLINICAL TRIALS**

All incentive payments, either monetary or non-monetary, in excess of budgeted project costs paid by sponsors in association with clinical trials or other sponsored projects must receive prior approval by the MCO IRB (if human research subjects are involved) and/or RGA. Approved incentive payments may NOT be paid directly to investigators or other project personnel, but must be deposited in the same MCO restricted account utilized for other monies received in support of that project.

It is the policy of MCO that neither it, nor its investigators or submits, will accept incentives or bonuses tied to the rate of recruitment of study subjects or to early enrollment of subjects in clinical trials, whether such incentives or bonuses are offered as a part of a research agreement or at any other time. For the purposes of this policy, the terms incentives and bonuses include anything of value. [NOTE: This does NOT preclude acceptance of clinical trials whose regular study budget is per capita based (e.g., \$2,000 per patient). It prohibits acceptance of bonuses or incentives above that amount which are linked to accelerated rates of subject accrual. Using the above study as an example, there might be a bonus or incentive offered of an additional \$1,000 for all subjects over 3 entered in each calendar month. In the case of this example, the \$2,000 per patient represents sponsor payments to cover the costs associated with conducting the research, and is acceptable, but the extra \$1,000 for the 4<sup>th</sup> and subsequent patients per month is NOT acceptable. The same would hold true for EXTRA money offered for early entry of subjects into studies (e.g., within the first 2 hours of onset of symptoms).]

[Excerpted from MCO Policy # 03-001 "GRANTS, CONTRACTS, CLINICAL TRIALS, AND ALL OTHER SPONSORED PROJECTS"]