GUIDANCE

FROM: DGSOM Clinical Trial Administration Office
DATE: August 16, 2012
RE: Limitations on Travel Reimbursement to Clinical Trial Subjects

Travel expense reimbursements to study subjects can pose compliance issues. This is because Federal law prohibits inducing Medicare beneficiaries to receive services and items that may be billed to Medicare and there are similar restrictions for State programs. Institutional review boards (IRB) traditionally have encouraged or even required reimbursement of research-related costs to subjects in all types of research studies, including clinical trials. These requirements are intended for example to: (i) minimize financial burden of participation, (ii) encourage equitable selection of research subjects from across the entire population, and (iii) allow subjects to comply with protocol requirements. Yet the government may interpret some arrangements to reimburse travel, lodging, or per diem expenses as unlawful inducements if associated with the delivery of standard of care services billed to insurance.

> While the fraud and abuse laws are not new, government enforcement of such laws is becoming more organized, targeted and common. See the recent press release from OIG on the matter **"Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly $4.1 Billion *Largest Sum Ever Recovered in Single Year"*** (see http://www.hhs.gov/news/press/2012pres/02/20120214a.html). For more information on the topic of Federal Fraud and Abuse laws, please see http://legal.uclahealth.org/body.cfm?id=26.

Nevertheless, reimbursement of travel expenses is permissible in some settings. For example, reimbursement typically may be made for unadvertised (i.e. not mentioned in subject recruitment materials or consent forms), reasonable transportation and lodging expenses:

- Associated with study visits that are necessary ***only*** because of the subject's participation in the study – that is, where the visit and any procedures performed are billed solely to the sponsor and not to Medicare or any private insurer such as Blue Cross or HealthNet; or

- Limited to $10 per incident and $50 aggregate per year; or

- Incurred by research participants who meet UCLA's indigent care guidelines (see HS 5310 http://www.mednet.ucla.edu/Policies/pdf/enterprise/HS5310.pdf).

TAKE AWAY:

Because the rules governing reimbursement are complex, and because sponsor payments may be made only under a contract approved by the DGSOM Clinical Trial Administration Office, study team members are advised that they should not 1) offer travel reimbursement to potential subjects or enrolled subjects, or 2) discuss reimbursement options with sponsors. Any such requests – regardless of whether the study team and/or sponsor believes that the propose reimbursement would be permissible due to previous experiences or guidance received from other institutions, etc., - must be vetted internally first in consultation with DGSOM Clinical Trial Administration Office and other UCLA stakeholders before any arrangements are made or offered. Other arrangements may be permissible as well, or may be eligible for government approval on a case-by-case or global basis.

For additional information or questions on this topic, please contact Helene Orescan, Director DGSOM Clinical Trial Administration Office.