October 5, 2009

To: Deans, Directors, Department Chairs and Executive Officers

In September 2008, we provided guidance about federal regulations that required reporting of clinical trials on the http://www.clinicaltrials.gov database by the "Responsible Party."

As of September 27, 2009, the "Responsible Parties" are required to report certain adverse event information when reporting and/or updating the results of the trial on www.clinicaltrials.gov. For specific details on the requirements we recommend that you view the materials located at: http://prsinfo.clinicaltrials.gov/AdverseEvents.html.

Please note that the "Responsible Party" for reporting results for PI-initiated clinical trials is the Principal Investigator. The "Responsible Party" for reporting sponsor-initiated clinical trials is the sponsor or the Sponsor’s designated PI. When the "Responsible Party" is a UCLA investigator, registration is done in the name of the individual, and not on behalf of The Regents. Additionally, a "Responsible Party" only has to register once. That registration number is then used for all clinical trials for which that individual is the "Responsible Party."

Sincerely,

Roberto Peccei
Vice Chancellor for Research

Alan Robinson
Executive Associate Dean
David Geffen School of Medicine