

Global Regulatory Enforcement Alert

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

Lane Kneedler

Counsel, Richmond
+1 804 344 3404
lkneedler@reedsmith.com

Pakapon Phinyowattanachip

Associate, Richmond
+1 804 344 3424
ppakapon@reedsmith.com

...or the Reed Smith lawyer with whom you regularly work.

New Federal Research Conflict of Interests Regulations

On September 26, 2011, the U.S. Department of Health and Human Services (“HHS”) issued new regulations governing the disclosure by faculty members and research staff of significant financial interests related to certain federal grants, and the reporting of “financial conflicts of interest” to certain federal agencies by colleges and universities that receive funding for Public Health Service (“PHS”)-sponsored research. See 42 C.F.R. § 50.601 et seq.

Colleges and universities that receive research funding from a PHS “Awarding Component,” including the National Institutes of Health (“NIH”), must be in compliance with the new regulations by no later than August 24, 2012.

The new regulations significantly expand the coverage of 1995 HHS regulations on the same subject. Significant changes to the regulations include: expanding the definition of “significant financial interest”; lowering the threshold for financial disclosure; requiring the disclosure of sponsored and reimbursed travel; expanding institutional responsibilities, including training requirements, reporting requirements, and retrospective review; requiring the inclusion of subrecipient institutions; and increasing public disclosure requirements.

Reed Smith has had recent and very relevant experience in developing compliance initiatives for colleges and universities to ensure that they adopt and implement institutional policies that meet the requirements of the new HHS regulations. Our attorneys have drafted institution-wide policies covering both scientific and non-scientific research and implementing procedures for determining whether faculty members and research staff have a significant financial interest affecting their research, for appropriately addressing and managing any such conflict, and for disclosing conflicts to the NIH and others, as required by the regulations.

Reed Smith lawyers also have had experience extending the implementation of conflict of interests policies beyond the hard sciences to include schools of social science, law, and business.

Restructuring State-Public University Relationships

Reed Smith has had extensive experience over the past decade in restructuring higher education in Virginia – both in restructuring the relationship between Virginia’s public universities and community college system and the central state agencies that oversee aspects of their operations, and in developing an improved framework for funding these institutions. This experience in Virginia can be helpful to public colleges and universities in other states where public funding of higher education has declined, or where central state agencies exercise close supervisory control or have oversight responsibility over such operational areas as procurement, capital projects, leases, information technology, and human resources.

Lane Kneedler leads the Reed Smith team on these two issues. He has had extensive experience representing public colleges and universities in restructuring their relationship with state government and in advising clients, including legislators, on conflict of interests issues. Lane was a principal draftsman of Virginia’s conflict of interests laws and higher education restructuring legislation. He is a former Professor and Associate Dean at the University of Virginia Law School, and still teaches a seminar at the Law School that covers conflict of interests involving state and local officials and employees. Pak Phinyowattanachip has had significant experience developing university research conflict of interests policies, and works with local school boards on conflict of interests issues.

About Reed Smith

Reed Smith is a global relationship law firm with more than 1,700 lawyers in 23 offices throughout the United States, Europe, Asia and the Middle East.

The information contained in this Client Alert is intended to be a general guide only and not to be comprehensive, nor to provide legal advice. You should not rely on the information contained in this Client Alert as if it were legal or other professional advice.

Reed Smith LLP is a limited liability partnership registered in England and Wales with registered number OC303620 and its registered office at The Broadgate Tower, 20 Primrose Street, London EC2A 2RS. Reed Smith LLP is regulated by the Solicitors Regulation Authority. Any reference to the term 'partner' in connection to Reed Smith LLP is a reference to a member of it or an employee of equivalent status.

This Client Alert was compiled up to and including April 2012.

The business carried on from offices in the United States and Germany is carried on by Reed Smith LLP of Delaware, USA; from the other offices it is carried on by Reed Smith LLP of England; but in Hong Kong, the business is carried on by Reed Smith Richards Butler. A list of all Partners and employed attorneys as well as their court admissions can be inspected at the website www.reedsmith.com.

© Reed Smith LLP 2012.

All rights reserved.