

THE UNIVERSITY OF NEW MEXICO + HEALTH SCIENCES CENTER

SCHOOL OF MEDICINE Office of Research

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General Clinical Research Center		Biosafety Compliance
		Human Tissue Översight Committee
		Conflict of Interest

28 August 2006

To: All SOM Faculty and Staff

From: Richard S. Larson, MD, PhD, Senior Associate Dean for Research, School of Medicine

Concurrence from: Ava Lovell, HSC Associate Vice President of Finance

RE: "Key Personnel" on Proposals

Audit findings at several universities and the stricter monitoring of effort reporting by the National Institutes of Health (NIH) have emphasized the need to pay careful attention to the Key Personnel that are listed on our NIH proposals.

These recent federal rulings have emphasized the importance of limiting Key Personnel on NIH grants. As you are probably aware, if any Key Personnel decrease their level of commitment by 25%, this must be pre-approved by the sponsor. Auditors are focusing their attention to the level of effort submitted on a proposal and comparing it to payroll reports, effort certifications, and updated "Other Support" submissions. This issue also translates to Key Personnel that are consultants or subawardees where UNM is required to actively monitor compliance. In order to limit audit exposure to the PI and institution (as well as limit paperwork and reporting), it is important to list only those individuals that are truly required.

The National Institutes of Health states that:

Unless otherwise specified in an agency announcement, senior/key personnel are defined as all individuals who contribute in a substantive, measurable way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included if they meet this definition.

Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a <u>substantive</u>, measurable way, whether or not salaries are requested. Typically, these individuals have <u>doctoral or other professional degrees</u>, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Key Personnel. Consultants should also be included if they meet the same definition. <u>Key Personnel must devote measurable effort (in person months) to the project whether or not salaries are requested</u>. "Effort of zero person months" or "as needed" are <u>not acceptable</u> levels of involvement for those designated as Key Personnel."

We have discussed this issue with officials from NIH and conclude that generally speaking only faculty who have a substantive scientific contribution are to be deemed "Key Personnel." The concept of "substantive and measurable" focuses on how interchangeable the person is in their role with particular focus on intellectual contribution and unique scientific knowledge.

Under this guidance generally speaking, technicians, post doctoral fellows, nurses, program managers, graduate students, and other related individuals, while still serving an important roll on the project, would not be typically included as "Key," but may be listed under "other contributors" unless there is an over whelming need to list them as key personnel. Consultants (including faculty) that are only providing guidance do not need to be included as key personnel. *Please remember that once an individual is listed as "key personnel," annual reporting and audits related to that individual will be in effect.*

Please call upon me if there are any questions.