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OFFICE OF THE PROVOST AND SENIOR VICE PRESIDENT—
ACADEMIC AFFAIRS

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, California 94607-5200

June 23, 2003

VICE CHANCELLORS FOR RESEARCH

Dear Colleagues:

I am writing to ask you to ensure that the appropriate offices on your campuses are aware of a final statement recently issued by the National Institutes of Health (NIH) regarding "Sharing Research Data" (attached, and also available at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html). Beginning with applications submitted on or after October 1, 2003, NIH will require investigators requesting $500,000 or more in direct costs in any single year to include a plan for sharing final research data or a statement why data sharing is not possible.

This new requirement stems from NIH's desire to promote timely release and sharing of final data for use by other researchers to advance the research enterprise. It applies to the sharing of final research data for research purposes from all types of research projects, including basic research, clinical studies, surveys, and other types of research supported by NIH. Though a data sharing plan is required, NIH reviewers will not factor the plan into the determination of scientific merit or priority score for the proposal.

NIH has posted a number of resource documents (including the attached Implementation Guidance) on its web site at:

http://grants.nih.gov/grants/policy/data_sharing/index.htm

The NIH Statement on Sharing Research Data includes language recognizing that data sharing may be complicated or limited, in some cases, by institutional policies, local Institutional Review Board (IRB) rules, and local, state and Federal laws and regulations. Data sharing plans must be developed with such policies and rules in mind. I would like to draw your particular attention to the need to take into account applicable rules pertaining to:

- Protecting the rights and privacy of human subjects. This includes complying with all applicable IRB rules and with the federal Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule pertaining to protected health information. In determining how best to make final research data available, investigators must consider the need to protect against disclosure of personally identifiable data (or to de-identify data when appropriate). NIH Implementation Guidance acknowledges the need to protect the rights and privacy of human subjects and discusses various possible methods for accomplishing this goal.

- Meeting the University's intellectual property and third-party obligations. This includes complying with the University's obligation under the Bayh-Dole Act to report to federal funding agencies on inventions resulting from the use of federal funds, as well as with third-party obligations resulting from extramural sponsored research agreements or material transfer agreements. In devising a data sharing plan, investigators must consider the need to allow adequate review for intellectual property and/or for proprietary information that must be protected prior to release of research data. NIH Implementation Guidance recognizes the need to protect patentable and other proprietary data (including in cases where co-funding is provided by the private sector) and notes that reasonable delays in disclosure of research findings may be needed to accomplish this goal.

Please encourage investigators to consult as needed with appropriate offices on your campus in devising their data sharing plans (e.g., IRB Chairs and HIPAA compliance officers regarding human subjects and HIPAA issues; Contracts & Grants officers regarding ensuring that data sharing plans are consistent with any third party obligations; Technology Transfer officers regarding intellectual property matters; campus counsel regarding questions about compliance with federal or state laws or regulations). NIH Implementation Guidance indicates that if an application describes a data-sharing plan, NIH expects the plan to be enacted and may take various actions to protect the government's interest in the case of noncompliance. Therefore, care should be taken to ensure that data sharing plans reference, where appropriate, measures that may be taken to ensure compliance with applicable University policies, local IRB rules, local, state and Federal laws and regulations, and third party obligations.

More detailed information about how to comply with the data sharing policy as it pertains to specific NIH Requests for Applications and Requests for Proposals will be provided in NIH solicitation instructions. In some cases, NIH program announcements may request data sharing plans even for applications with budgets of less than $500,000. NIH is encouraging investigators to discuss their proposed data sharing plans with NIH Institute or Center staff prior to submission of their applications.

I would appreciate your disseminating this letter as appropriate on your campus to make sure that investigators and the offices with whom they may need to consult are aware of the new NIH data sharing requirement.

Sincerely,

Lawrence B. Coleman
Vice Provost for Research

Enclosures

cc: Provost King
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