November 16, 2004

Elias A. Zerhouni, Director
National Institutes of Health
Office of Extramural Research
6705 Rockledge Drive, Room 350
Bethesda MD 20892-7963
Submitted via email to: PublicAccess@nih.gov

RE: Enhanced Public Access to NIH Research Information
(Notice No. NOT-OD-04-064 and NOT-OD-04-070)

Dear Dr. Zerhouni:

I am writing on behalf of the University of California system to respond to the National Institutes of Health (NIH) Notice regarding Enhanced Public Access to NIH Research Information (Notice No. OD-04-064 as modified by NOT-OD-04-070). The Notice announces that NIH plans to request grantees and supported Principal Investigators to provide NIH with electronic copies of all final version manuscripts upon acceptance of those manuscripts for publication if the research was supported in whole or in part by NIH funding. The Notice announces that NIH plans to make these manuscripts freely available to the public through PubMed Central (PMC), NIH's digital repository for biomedical research, six months after an NIH supported research study's publication, or sooner if the publisher agrees.

The University of California strongly supports efforts to make the results of federally funded research widely available, and shares the NIH's goal of ensuring that scientific information arising from NIH-funded research is made available in a timely fashion to other scientists, health care providers, students, teachers, and members of the public. Wide and open dissemination of research results is critical to the advancement of science.

As a major public research institution, the University of California community includes researchers, students, and practitioners who both create and use the new knowledge that results from NIH-funded studies. In addition, our community includes scholars who are both creators and users of the peer-reviewed scholarly journals that play an important role in ensuring the quality and integrity of the scientific information that is disseminated to the wider scientific community. Thus, we have an interest in policies that both encourage wide and open dissemination of research results and that recognize and preserve the critical role of peer-reviewed scholarly journals.

We appreciate that NIH is seeking comments before implementing its proposal, and urge the agency to work closely with the research community and with the scholarly publishing community to devise ways to minimize potential implementation burdens and unintended consequences and to achieve the goal of expanded public access in ways that preserve the quality of published scientific information. There are many in our

community who believe it is timely to explore new models that take better advantage of the new capabilities and favorable economics of digital publication. To this end, the NIH proposal appears to be a promising experiment, with the potential to help promote the goal of expanded access to research results. However, we believe there are a number of academic and operational issues that merit the agency's close attention as it considers how to move forward. We offer the following points for consideration, and urge the agency to (1) carefully review and monitor these issues in consultation with the stakeholder community; and (2) to the extent that it does move ahead with implementation, to prepare criteria and plans for redirecting the experiment if outcomes prove undesirable.

Academic Issues

Maintaining the quality of scientific information
It is critical that mechanisms for assuring the quality of scientific publication, including peer review, be maintained. We appreciate that NIH has acknowledged the importance of this factor in its proposal, and note that the statements issued by both the National Academy of Sciences (NAS) and the Association of American Universities (AAU) have also highlighted this issue.

Ensuring the financial sustainability of biomedical scholarly publishing
The financial consequences the NIH proposal would have for biomedical publishing are uncertain. Some publishers believe that making articles available on PMC within 6 months of publication could adversely affect subscription sales, which is of particular concern for non-profit society publishers, who depend on publishing revenue to support the operations of their societies and may not have adequate financial reserves to cushion any short-term effects from the NIH proposal. This point is emphasized in both the AAU and NAS statements, and we appreciate that NIH has acknowledged and pledged to work on addressing this issue.

Maintaining the integrity of the research record
The possibility that implementation of the NIH proposal could result in the persistent availability of multiple versions of a research report (at minimum, the author's final manuscript deposited in PubMed Central and the publisher's version) has raised concerns. While there are technical means to address the problem, it is critically important that it be given consideration; we agree with the emphasis the NAS statement placed on this issue.

Operational Issues

In most cases, the University itself, rather than the faculty member or student is the party that contracts with NIH for "research grants, cooperative agreements, contracts, as well as National Research Service Award (NRSA) fellowships." As the contracting party, the University is responsible for award terms that are contractual requirements (though we recognize and appreciate that the proposed NIH policy is being framed as a request to

grantees). There are a number of operational implementation concerns we believe merit attention, including the following:

Institutional administrative burden
Institutions will incur a burden in supporting the proposed NIH policy, including a) communication with current and prospective PIs and with NIH, b) administrative procedures to monitor compliance, and c) operational capabilities to assist with formatting and submitting manuscripts. It is desirable that NIH, in its planning, take steps to i) minimize the costs imposed on institutions, ii) consult with institutions in the development of procedures, and iii) consider means to compensate institutions for additional costs.

Relationships to institutional repositories
Many institutions currently operate or are planning to establish institutional repositories to store and provide access to their faculties' research output. The University of California, for example, operates the eScholarship Repository (http://repositories.cdlib.org/escholarship/), which hosts working papers and pre-prints, peer-reviewed journals and monographic series, and seminar series, and plans to host journal article post-prints as well. It would be desirable if UC's NIH grantees could satisfy the NIH submission request by depositing their manuscript in the eScholarship Repository. UC, in turn, could for each article either a) provide PMC with XML metadata for the article, with a link to the copy hosted at UC, or b) reformat the article to comply with PMC requirements, and submit to PMC on behalf of the grantee and Principal Investigator.

Procedures for deposit of author manuscripts
Current specifications for deposit of articles to PubMed Central require that submitted articles be formatted in SGML or XML in conformance with an established Document Type Definition (DTD). These specifications were developed for publishers submitting their content to PMC, and will likely not be appropriate for institutions or, especially, individual grantees preparing manuscripts for submission. NIH will need to develop simple technical and administrative procedures and supporting technologies that allow grantees to submit manuscripts in their native formats, or can automatically convert common native formats to those required for PMC.

Intellectual property considerations
The NIH proposal may raise both substantive and implementation issues relating to intellectual property. For example, some licensing officers raised questions about whether submission to and publication in PubMed Central could affect the ability to claim foreign patent rights (given the diminished ability to receive patent protection if enabling elements of an invention have been disclosed to someone skilled in the art of the subject matter). NIH might consider provisions assuring confidentiality of archived data prior to publication to help address this issue (e.g. similar to how NIH handles pre-award grant applications), and might also consider specifying that agreement from the institution as well as the publisher should be secured in order for PMC to publish sooner than specified in the proposal. There is also some question as to whether the NIH

proposal might lead to a need for authors to negotiate contract language with their publishers reserving a right to provide the manuscript to NIH for publication in PMC. With respect to this point, there is concern that authors may not have the legal expertise to draft such assignments (typically, university counsel are not involved in negotiating such matters since faculty, not the institution, own the copyright). NIH should explore IP-related issues that may be raised by its proposal.

Communication
It will be critically important for NIH to communicate with current and prospective grantees and PI's, and their institutions, about the nature of its request and means available for compliance. We understand and appreciate that NIH is already planning to contact funded investigators to inform them of its plans.

Effect on NIH award decisions
It will be critically important for NIH to fully articulate the role that compliance with its request will play in the grant progress review and close-out process and otherwise in determining or influencing the awarding of NIH funds, and to ensure effective consultation with the affected academic and institutional communities in developing any related policies and procedures.

Relationship between faculty publishing practices and NIH reporting requirements
The requirement for deposit "upon acceptance for publication" is not aligned with the customary schedules and requirements for investigator or institutional reporting to NIH, placing an extra burden on grantees and their institutions to remember to take action at times outside of the normal NIH reporting cycles. The burden on grantees and institutions of identifying and submitting eligible articles may be amplified by the facts that a) in many cases, publication of results can occur long after the period of performance for the supporting NIH award has ended, and b) published papers may draw on a variety of research findings, only some (perhaps a small minority) of which were developed with NIH support.

Research publications other than journal articles
PubMed Central's website describes PMC as "the U.S. National Library of Medicine's free digital archive of biomedical and life sciences journal literature" (http://www.pubmedcentral.nih.gov/). While the vast majority of research findings resulting from NIH funding make their way to publication by way of journal articles, the proposed policy applies to "all final version manuscripts upon acceptance for publication...." It is not clear how the NIH proposed policy might apply if the resulting publication were something other than a journal article. This may be an issue NIH will wish to address.

In sum, the University supports NIH's goal of enhancing wide and open public dissemination of research results, but advises careful consideration of the above issues

and ongoing consultation with the research and scholarly publishing communities as the agency determines how best to achieve its goal. We appreciate the opportunity to comment on NIH proposal.

Sincerely,

Lawrence B. Coleman
Vice Provost for Research

cc: Provost Greenwood
Academic Council Chair Blumenthal
Vice Provost Zelmanowitz
AVP Sudduth
Executive Director Tucker