

American Cancer Society, American Diabetes Association, and American Heart Association response to NIH Public Access Proposal

The American Cancer Society, American Diabetes Association, and American Heart Association are the largest voluntary health organizations dedicated to eliminating cancer, diabetes, and cardiovascular disease as major health problems. These organizations' strategies for achieving these goals include providing information to people and families affected by these chronic diseases in order to facilitate informed decisions, delivering programs and services to these individuals and families, improving access to care and quality of life, and providing information and continuing education programs to healthcare professionals that focus on these diseases and their treatment.

Our organizations also conduct intramural research programs and distribute extramural research grants. Thus, exchange of information among researchers, clinicians, and the public is central to our missions. Similarly, we are dedicated to serving the needs of patients and their families and recognize their critical need for information as they face these devastating diseases. For this reason, we are responding to the recent proposal from the National Institutes of Health (NIH) regarding public access to research articles describing NIH-funded research and are mindful of the needs of these varying constituencies.

We strongly support the goal of increasing the public's access to information that can empower people in making informed decisions about their health. However, in considering implementation of the NIH proposal, we would want to ensure that these actions do not inadvertently detract from the goal of conducting and promoting quality research that ultimately improves patient health. As such, we recommend a thorough analysis of the current NIH proposal and would suggest that this analysis consider the following issues.

1. **Integrating information with existing online literature.** Without doubt, patient information is a very important health priority for public and private stakeholders. In facilitating informed health and healthcare choices, it is important to identify the content gaps of greatest public health significance in order to assess the value of any proposal. Online health information has become increasingly important, and many millions of web pages on health issues are provided by the NIH, CDC, FDA, and other federal and state agencies; by nonprofit voluntary health organizations such as the American Cancer Society, American Diabetes Association, and American Heart Association; by medical schools and specialty organizations; and by general and health-specific news and information sites.
2. **Assuring the integrity and quality of the information.** Although we strongly support progress toward greater availability of clinical information at lower or no cost to patients, a system that archives accepted, unedited author manuscripts—including

large volumes of preclinical research—may not meet optimally the needs of patients seeking access to clinical articles not available by other means. The number and significance of changes made during copyediting can be substantial. For this reason, we believe one of the most important sections of the NIH proposal—and one that must be carefully reviewed—is the provision which would allow for an original, pre-publication submission to be replaced by the final copy-edited version.

3. **Ensuring a workable, accessible, and easily searchable resource.** Additionally, it is important for articles to appear in the context of published “errata,” as they would in a journal website, and for research articles to appear in the context of editorials that are occasionally written in response to the authors’ conclusions. Should NIH go forward with this proposal, NIH would need to consider ways to standardize and categorize the information presented, so that the repository is a workable, accessible, and easily searchable resource. Without such safeguards, the database will fail to fulfill its mission of improving the dissemination of information. As such, any proposals that are advanced with the goal of promoting informed healthcare decisions by the public should be considered on the basis of a thorough and scientific needs assessment and appropriate market research and field testing.
4. **Enhancing access without diverting/reducing research dollars.** We note that the costs of enlarging and maintaining the digital repository where these articles would reside remain unknown. Any proposal needs to be backed by an analysis of the associated capital and human resources needs. Furthermore, we firmly believe that the maintenance of such a repository should not impinge on any NIH research funding. As such, we strongly recommend that NIH give assurances that such a repository will be funded either 1) through re-direction of administrative funds within the Office of the Director or the National Library of Medicine, or 2) through a separate budget line that does not reduce current research funding or future funding growth.
5. **Enhancing access without jeopardizing robust peer review.** We encourage NIH to work closely with journal publishers to ensure that the quality assurance offered by the peer review process is not jeopardized with this new proposal. The peer review process helps promote quality science by ensuring that research methods, results, and conclusions are valid.

In summary, the American Cancer Society, American Diabetes Association, and American Heart Association recognize the importance of providing information on health and healthcare topics to promote informed choices by patients and the general public, as well as the central role of information in guiding research. We need a balanced policy that preserves the role of journals and publishers in a way that does not undermine good research, but that rather ensures that stakeholders can benefit from the wealth of research supported by US taxpayers. We would encourage NIH to conduct an analysis of implementing such a repository to better understand its costs, integration with existing online literature, and impact on provider and patient needs. Such an analysis will help

ensure that this public health initiative preserves what is working in our current system, while moving forward to promote the common good.

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