

UC Office of the President

U.S. Department of Health and Human Services (HHS)

Title

UC Comments on Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants (NOT-OD-26-113)

Permalink

<https://escholarship.org/uc/item/5dr3q55j>

Journal

N/A

Author

UC Office of the President

Publication Date

2026-10-23



OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200

Submitted electronically via

<https://osp.od.nih.gov/comment-form-draft-sharing-summary-results-policy/>

October 23, 2026

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630,
Bethesda, MD 20892

**RE: University of California System Comments on Draft NIH Policy on Sharing
Summary Level Study Results with Clinical Research Participants (NOT-OD-26-
113)**

To Whom It May Concern:

On behalf of the University of California system (UC), we appreciate the opportunity to comment on the National Institutes of Health (NIH) [Draft Policy on Sharing Summary Level Study Results with Clinical Research Participants \(NOT-OD-26-113\)](#), issued August 27, 2026.

UC supports NIH's intention to strengthen the relationship between the research community and clinical research participants by providing meaningful opportunities to understand how their contributions have advanced scientific knowledge. With ten campuses, six academic health centers, an Agriculture and Natural Resources division, and three affiliated U.S. Department of Energy national laboratories, UC educates nearly 300,000 students, employs more than 260,000 faculty and staff, and conducts over \$7 billion in annual research. As an extensive research enterprise, and a longstanding NIH partner, UC encourages NIH to develop well-considered, responsible and effective approaches for sharing research results with clinical research participants.

In preparing these comments, UC consulted with its campus Human Research Protection Programs. UC's comments address the purpose, definitions, scope, effective date, and responsibilities sections of the Draft Policy, as well as the supplemental guidance and implementation considerations identified in the request for information (RFI).

UC Urges NIH to Defer to IRBs in Determining Whether to Share Results

UC urges NIH to defer to IRBs in determining whether summary-level study results should be shared, rather than establishing a uniform requirement that applies in every case. IRBs are best positioned to evaluate study-specific considerations, including participant expectations established through consent, privacy and re-identification risks, the sensitivity of the research, and the potential for disclosure to cause harm or confusion. For example, participants in end-of-life studies or studies involving sensitive genetic testing may prefer the option to decline follow-up information. NIH should provide clear principles and

criteria but allow IRBs to determine whether results should be shared and, if so, the appropriate timing, content, format, and method of communication.

Pilot Test the Summary Sharing Approaches

Sharing summary-level study results with clinical research participants is a socially responsible endeavor. At the same time, the proposed requirement represents a significant change for investigators and institutions, with implications for participant privacy, scientific communications, institutional operations, and research administration.

For these reasons, UC strongly recommends that NIH conduct a meaningful pilot before making any final requirement to share summary-level results enforceable. The pilot should engage patient partners to assess what makes a summary appropriate and how participants understand and use the information. It should also evaluate effective dissemination methods, including the use of plain language, and identify potential privacy, ethical, scientific, operational, and administrative risks. In addition, the pilot should test the proposed timelines, exception process, NIH-based and institutional repository options, documentation requirements, and use of artificial intelligence. The pilot would give NIH and the research community an opportunity to refine best practices and supplemental guidance and establish workable processes for preparing, reviewing, disseminating, and documenting summary-level results before the Draft Policy takes effect.

Scope of the Policy

The Draft Policy applies to all clinical research, including clinical trials. NIH's definition of clinical research within the Draft Policy is broad and may encompass research for which sharing summary results is not appropriate or feasible. The pilot period should evaluate the scope of the Draft Policy.

Patient-oriented research involving direct interaction with human subjects is most suited to implementation of a summary-sharing requirement. By contrast, research that does not involve direct interaction with subjects should generally be excluded from the summary-sharing requirement. Similarly, research involving samples or data under an informed-consent waiver may not be appropriate for return of results. Waiver of documentation prevents re-identification, and studies that collect highly sensitive data thrive only when anonymity is guaranteed. NIH should consider blanket exemptions for categories of research that clearly fall outside the intended purpose of the Draft Policy, rather than requiring project-by-project determinations.

A major concern with the broad definition of clinical research is that some categories of research do not currently have the infrastructure necessary to facilitate a return of results. For example, ClinicalTrials.gov provides an established platform for registering clinical trials and reporting certain summary results, and NIH expects NIH-funded clinical trials to use it; however, federal reporting requirements apply only to specified applicable clinical trials under [42 CFR Part 11](#). Under the Draft Policy, many studies would not meet NIH's definition of a clinical trial and therefore would not have a generally applicable platform or standardized process for sharing summary results with participants. Before implementing the Draft Policy broadly, NIH should assess whether ClinicalTrials.gov can accommodate these studies or whether it is necessary to adopt another database for reporting summary-level research results with the appropriate standards and resources. It would be unwise to implement the Draft Policy without first determining how

the requirement can be carried out responsibly and effectively across the full range of studies within the proposed scope.

Timelines for Sharing of Summary Results

The Draft Policy's timelines for sharing summary results should take into consideration meaningful differences among clinical trials and other forms of clinical research. For example, multi-site clinical trials may involve different enrollment timelines, completion dates, data-cleaning processes, and institutional or sponsor timelines, making a uniform deadline difficult to apply. Also, requiring communication by reference to the primary completion date may result in findings being shared before adequate internal review, peer review, or publication. Early dissemination could affect publication strategies or potentially be viewed as prior publication. NIH should clarify how the Draft Policy will interact with ClinicalTrials.gov reporting and other existing obligations and should allow institutions and investigators sufficient time to ensure that summaries are scientifically accurate, appropriately reviewed, and suitable for participants.

Exceptions to the Summary Sharing Requirement

Within the Draft Policy, NIH states that “[i]f sharing summary level study results with research participants is *justifiably not appropriate* and summary level study results will not be shared, exceptions may be requested, subject to NIH Institute, Center, or Office (ICO) approval” (emphasis added). The “justifiably not appropriate” exception requires clearer criteria and procedures. NIH should explain what circumstances would qualify for an exception and identify examples of circumstances in which sharing may not be appropriate. Examples may include research involving identifiable study populations, substantial re-identification risks, sensitive conditions, terminated studies, and circumstances in which release could cause harm, confusion, or an unreasonable invasion of privacy. Additionally, NIH should consider exceptions for studies of minors, including when the parent has consented/child assented and the minor is now an adult when results are ready for return. Institutions should retain flexibility to make exception determinations under defined criteria, with IRBs authorized to determine whether summary-level results should be released, rather than requiring NIH approval.

Provide Sample Content in Supplemental Guidance

The Draft Policy's supplemental guidance should provide model templates and minimum content requirements. Because “plain language” is inherently subjective, standardized guidance is necessary to reduce variability across institutions and studies. Examples should address different study designs and populations, including clinical trials, observational studies, basic experimental studies involving humans (BESH) studies, behavioral research, epidemiological studies, health services research, and longitudinal studies. Additionally, NIH should consider when translations are necessary, such as when studies use a language other than English or the participant pool consists of non-English speakers.

Due to the wide variety in studies, institutions and their IRBs should retain flexibility to determine the appropriate reviewer, format, dissemination method, and timing for a particular study. NIH should not require a single review pathway or uniform dissemination method when study design, participant population, scientific context, or privacy considerations warrant a different approach.

Participant Privacy and Records Retention

NIH should clarify that the Draft Policy does not create a new obligation to retain identifiable participant information solely for purposes of sharing summary results. Institutions should be permitted to follow the retention periods required by applicable law, institutional policy, the IRB-approved protocol, and

established records-management practices. In many studies, participants may no longer be reachable or appropriate to contact after study participation ends, particularly where contact information is outdated, participation has ended, or renewed contact could create privacy or safety concerns. For example, if results are sent to a participant's old mailing address, that could lead to a breach of privacy. NIH should permit institutions to document reasonable, good-faith efforts without requiring indefinite retention of identifiable information.

Funding, Infrastructure, and Implementation Period

NIH should recognize and fund the actual costs of implementing the Draft Policy, including scientific and institutional review, plain-language drafting, participant and community consultation, translations, interpretation, accessibility services, secure communications, staff training, recontact efforts, documentation, and quality control. If NIH requires a centralized repository, institutions may also incur costs for system integration, data governance, cybersecurity, maintenance, records management, and technical support. These costs should be allowable and appropriately included in awards; the Draft Policy should not become an unfunded mandate.

The proposed six-month implementation period is insufficient for institutions to establish policies, assign roles and responsibilities, develop templates and workflows, train personnel, and build or integrate necessary infrastructure across a large and diverse research enterprise. NIH should provide substantial supplemental guidance and a realistic transition period before enforcement begins. The effective date should be established only after institutions have had an opportunity to review their current processes, participate in pilot testing, provide feedback to NIH, and develop effective systems to support compliance with this Draft Policy.

Conclusion

UC supports the underlying principle that research participants should be treated as partners and should have meaningful opportunities to learn what was accomplished through their participation. The Draft Policy's success, however, will depend on whether NIH establishes a practical, flexible, and adequately supported framework. A pilot period, standardized dissemination tools and content, clearer timelines and exceptions, strong privacy protections, appropriate funding, and an adequate implementation period would allow NIH to advance transparency and public trust while avoiding disproportionate administrative burdens and unintended consequences for participants, investigators, institutions, and the greater public.

Thank you for considering UC's comments. If you have any questions regarding these comments or would like additional information, please contact Ruchika Dhussa, Senior Research Policy Manager, Research Policy Analysis and Coordination, at Ruchika.Dhussa@ucop.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'Deborah Motton', written over a horizontal line.

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis & Coordination
University of California Office of the President