

Submitted Electronically via Regulations.gov

October 26, 2026
Office of Science Policy
National Institutes of Health

Re: NOT-OD-26-113 — Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants

Dear NIH Office of Science Policy:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on NIH's proposed policy for sharing summary level study results with clinical research participants. AMIA is the professional home for more than 6,400 clinicians, researchers, educators, data scientists, and health technology leaders dedicated to advancing health and healthcare through informatics. AMIA supports making understandable study summaries a routine part of NIH-supported clinical research. The final policy should pair this expectation with participant choice, accessible communication, and adequate resources for researchers and institutions to carry it out.

AMIA brings expertise in informatics, the study and application of information and computer sciences to improve health, healthcare, and biomedical research, to the collection, analysis, and communication of health information. Guided by our mission to transform healthcare through trusted science, education, and the practice of informatics, we support making research findings understandable and useful to the people who contribute to their discovery. Our Public Policy Principles and Policy Positions provide the foundation for these comments, particularly Patient Empowerment, Health and Healthcare Equity, and Data Sharing in Research.¹ Our Health and Healthcare Equity principle specifically calls for relevant data to be shared back with those engaged in research. We recommend the following approaches to the policy and its supplemental guidance.

Participant Preferences and Experiences

NIH should recommend that study teams work with participants and community representatives to identify the questions a summary should answer and test whether the explanation is understandable. Engagement should include people with varied education and literacy levels, languages, disabilities, and access to technology. Researchers should budget for this work and compensate participant and community advisers for their contributions.

At enrollment, participants should receive a brief explanation of the results they can expect, the anticipated timing, and how to update their communication preferences. The final policy should clearly establish a choice to receive or decline summaries and permit participants to change that choice. Declining a summary should have no effect on research participation or access to care. The participant-choice provision in Section V needs clearer wording to remove ambiguity about this expectation.

Delivery should accommodate participant preferences through options such as email, postal mail, accessible web content, telephone, or a trusted community partner. NIH should discourage approaches that require participants to create new accounts, create passwords, purchase technology, or navigate

¹ American Medical Informatics Association. AMIA Public Policy Principles and Policy Positions. 2024–2029 Priorities. 2025 version. Patient Empowerment, pp 4–6; Data Sharing in Research, pp 15–16; Health and Healthcare Equity, pp 36–38. <https://brand.amia.org/m/7094a39156542fdf/original/AMIA-Public-Policy-Principles-2025.pdf>

multiple portals. Study teams should also provide contact information for questions, with a realistic description of the support available and a low-burden process for getting their questions answered.

Best Practices for Researchers

Provide a Consistent Core Summary with Room for Adaptation

NIH should develop optional templates that explain the research question and hypothesis, who took part, what the study did, its principal findings, and what those findings mean. Summaries should include important harms, uncertainty, and limitations. They should explain findings showing no benefit or inconclusive findings with the same care as positive results. Where numbers are useful, understandable absolute quantities and well-tested visuals should accompany the narrative. Where studies include percentages related to treatment benefits or harms, they should be accompanied by clarification regarding absolute vs. relative differences, as well as number needed to treat (NNT), and number needed to harm (NNH). Likewise, for research involving tests, explanations such as test sensitivity, specificity, and predictive value (PV+, PV-) should be included. Explanation of statistics such as confidence intervals (CI) should be included where relevant to help research participants understand the statistical significance of the results, and the relationship between statistical and clinical significance.

Guidance should address how teams select secondary or exploratory findings without overstating their importance or selectively presenting favorable outcomes. For longitudinal, adaptive, and multisite studies, NIH should offer examples of when an interim update is appropriate and when a complete summary can be responsibly prepared. Researchers should explain when findings are preliminary or have not undergone peer review, and maintain a process for correcting material errors.

Each summary should clearly identify the study, the period covered, the summary preparation date, and where participants can find further information. It should distinguish findings about the study population from an individual participant's results. Researchers should explain when the findings cannot support a change in an individual's care and direct personal treatment questions to an appropriate clinician.

Make Summaries Accessible and Culturally Appropriate

NIH should provide guidance on translation, disability access, and communication of numerical risk in absolute and relative terms. Readability scores can inform editing, but participant testing should help determine whether the message is understandable and useful. Infographics should be included where relevant to make results more easily understandable to participants. Accessible HTML, large print, audio, and captioned materials should be available when needed. Translation should undergo qualified review, including attention to scientific meaning and cultural context.

Protect Privacy Throughout Communication

Delivery practices should account for the possibility that a message, shared device, or mailing could reveal participation in a sensitive study. Contact preferences and authorization for communication with caregivers or representatives should be recorded and respected. Guidance should address changes in guardianship, participants reaching adulthood, loss of decision-making capacity, and deceased participants. Community-level dissemination should complement the opportunity for individual access where feasible and appropriate.

NIH should provide examples of assessing disclosure risks in small studies and subgroup summaries. Teams should consider whether an aggregate result could identify a participant when combined with other

information, while preserving the summary's usefulness. Researchers should not disclose identifiable participant information through public summaries or distribution lists.

Set Conditions for Responsible Use of Automation

Supplemental guidance should address AI-assisted drafting or translation where researchers elect to use these tools. A qualified human should verify the final summary against the study findings, including numerical accuracy, uncertainty, and omissions. Institutions should protect confidential inputs, assess performance across languages and populations, and document material AI assistance. NIH should retain investigator and institutional accountability for the communication rather than relying on a tool's output.

Implementation Needs

Fund the Full Communication Process

NIH should clarify how applicants can budget reasonable costs for preparing and sharing summaries and how institutions can support work that continues after an award ends. Relevant activities include participant consultations, writing and scientific review, translation, accessibility services, maintaining contact preferences, distribution, and responding to questions. Support should reflect study duration, number of sites, language needs, and the complexity of the findings. AMIA does not propose a uniform dollar amount because these costs will vary substantially across studies.

NIH should provide sample budget categories and seek implementation cost data from institutions of different sizes and resource levels. Small research teams should have access to shared services and technical assistance. A requirement to communicate with participants should come with a practical way to sustain the staff and systems needed to complete that communication.

Build Reusable Infrastructure and Avoid Duplicate Work

NIH should support reusable templates and tools that can work with existing research management systems. A core set of structured fields could identify the study, summary version, language, date, and location while allowing flexibility in how the results are explained. NIH should develop these specifications with participants, research teams, and informatics professionals and test them before recommending broad adoption.

Institutions should be able to reuse verified information from study records and existing results submissions, with human review of the participant-facing text. The policy should avoid requiring researchers to manually reenter the same information in several systems. Optional integration with patient portals may be useful where appropriate permissions and relationships exist; participants should also have a way to receive results outside a health system's portal.

For multisite studies, NIH should allow a coordinated summary and clearly assigned responsibilities for scientific review, translation, and local distribution. Institutional planning should identify who will retain responsibility if the principal investigator changes institutions or the research team dissolves.

Document Meaningful Efforts Without Shifting Burden to Participants

NIH should distinguish preparation of a summary, an offer to receive it, delivery attempts, and confirmed receipt. Compliance should recognize reasonable, documented efforts when participants decline, cannot be reached, or choose not to open a message. Institutions should not need to compel a participant response or collect unnecessary information to prove that results were read.

The closeout process should capture a small set of information, such as the summary's availability, distribution date or status, and any approved exception. NIH should clarify how researchers will report later completion if only a status update is available at closeout. Evaluation should include voluntary participant feedback on understanding and usefulness, with attention to differences in access. These assessments should use existing records where possible and avoid creating a new reporting system for every study.

Clarifications Needed in the Final Policy

NIH should accompany the final policy with examples addressing which research is covered, including secondary research and studies whose teams do not hold participant contact information. Guidance should explain how the clinical research definition and its stated exclusions apply, how to handle overlapping awards, and what researchers should do when existing consent terms limit recontact. NIH should not encourage collection of additional identifiers solely to contact participants without considering consent and privacy implications.

Timing guidance should identify when summaries and updates are due for long-running studies and work supported through successive awards. For studies whose analyses continue beyond the performance period, NIH should specify how teams communicate a revised schedule and who remains responsible for final distribution. A journal publication should not be a prerequisite for sharing findings that have been adequately analyzed and reviewed.

Exceptions should follow transparent, consistent criteria across NIH Institutes, Centers, and Offices. NIH should distinguish an approved exception from an unsuccessful delivery attempt and provide examples of appropriate alternatives when direct sharing poses a privacy or safety concern. Researchers should also know how to request an exception when a problem emerges after enrollment. Lack of planning should not become a routine reason to withhold results.

NIH should issue templates and operational guidance before the policy takes effect and assess whether the proposed transition period allows institutions to update systems, budgets, and staff training. Early implementation should emphasize technical assistance and opportunities to correct deficiencies, with enforcement proportionate to the nature and persistence of noncompliance.

AMIA supports NIH's goal of returning understandable findings to the people whose tax dollars make research possible. A final policy that respects participant preferences and funds workable communication processes can make this responsibility sustainable across the research enterprise. We appreciate NIH's consideration of these recommendations. Please contact Tayler Williams, Senior Manager of Public Policy, at twilliams@amia.org with any questions.

Sincerely,



Eileen Koski

Chair, AMIA Public Policy Committee