AMERICAN PSYCHOLOGICAL ASSOCIATION

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Lyric Jorgenson, Ph.D.
NIH Associate Director for Science Policy
Office of Science Policy
Office of Extramural Research
National Institutes of Health
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

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

*Submitted electronically via email: SciencePolicy@od.nih.gov and through the NIH response portal*

Dear Dr. Jorgenson:

The American Psychological Association (APA) appreciates 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). APA is the nation's largest scientific and professional nonprofit organization representing psychology, with 190,000 members and affiliates, including clinicians, researchers, educators, consultants, and students in psychological science. APA's mission is to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

APA strongly supports the policy's central premise: people who contribute their time, experiences, and data to research should receive timely, accurate, accessible, and understandable information about the study's findings. This practice reflects respect for participants, can strengthen trust in research, and may improve recruitment, retention, and the relevance of future studies.

APA recommends that NIH finalize the policy with safeguards that make results sharing meaningful across the full range of NIH-supported clinical research, including behavioral, psychological, social, observational, community-based, longitudinal, pragmatic, and mixed-methods studies. The final policy should set clear expectations, define its scope, distinguish aggregate findings from individual clinical information, and account for the practical demands of implementation.

This position is supported by a growing but still limited evidence base. Researchers and participants associate returning results with respect, trust, recognition of participants' contributions, better understanding and use of research, stronger recruitment and enrollment, and greater community

support (Bagita-Vangana et al., 2025; Long et al., 2019; Melvin et al., 2020). In a rights-informed study conducted with two communities in Kerala, India, participants interpreted the failure to share earlier findings as a sign that researchers were not interested in improving their circumstances; reciprocal engagement, by contrast, helped participants take ownership of the findings and use them to advocate for change (George et al., 2023).



However, both aggregate and individual return-of-results practices remain empirically underdeveloped. Wong et al. (2018) characterized the field as largely uncharted and untested and called for systematic evidence on what information to return, when to share it, and how it can create value for participants. Similarly, in a scoping review of practices, preferences, and challenges related to sharing aggregate study findings with research participants, Idnay et al. (2025) found that only four of the 12 included studies evaluated actual dissemination and that the included studies provided limited representation across socioeconomic, educational, and literacy groups. These findings support continued learning from implementation.

Accordingly, APA offers the following recommendations:

**Retain a broad commitment to returning results while allowing study-appropriate flexibility -** APA supports offering summary-level results to participants by default while allowing the delivery method to reflect the study and population. In the studies Idnay et al. (2025) reviewed, participants generally preferred mailed letters and face-to-face meetings over online approaches; global evidence indicates that researchers in varied settings use written summaries, group presentations, and workshops differently (Bagita-Vangana et al., 2025). Melvin et al. (2020) identified differences in channel and format preferences among adolescents, young adults, and older adults.

NIH should therefore permit written summaries, secure electronic communications, accessible web content, community meetings, videos, infographics, and other appropriate formats. Where feasible, investigators should offer multiple options and avoid relying exclusively on digital communication. Regardless of format, the information must be understandable, accessible, and responsive to the participating populations.

**Require plain-language, accessible, and culturally responsive communication;** summary results should be understandable to the populations that participated in the research, not merely simplified scientific abstracts. NIH should require communications to explain the study's purpose, methods, principal findings, limitations, uncertainty, and implications without overstating causality or clinical significance. Materials should account for health literacy, language access, accessibility for people with disabilities, cultural context, and varying levels of scientific familiarity. This matters because, for example, the studies Idnay et al. (2025) reviewed rarely assessed literacy and included limited socioeconomic and educational diversity.

NIH should encourage investigators to co-develop and test materials with participants and communities, with support from community advisers, psychologists, health-communication experts, and other relevant professionals. Melvin et al. (2020) demonstrated the value of participant and researcher input in designing communication prototypes, while George et al. (2023) found that tailored formats and active engagement helped reduce power disparities, support shared interpretation and development of recommendations, and enable communities to use findings for advocacy.

**Clarify the policy's scope and key definitions -** A 2025 systematic review of 96 studies found that participants generally expected results regardless of study outcome and associated disclosure with respect, trust, and recognition of their contributions (Bagita-Vangana et al., 2025). Providing an understandable account of what a study found is therefore not merely a communication enhancement; it is an evidence-supported practice that advances respect, reciprocity, transparency, and accountability. A clear NIH-wide policy can help convert broad ethical agreement into consistent practice.



Accordingly, APA recommends that the final policy clearly define "clinical research participant," "study completion," "summary-level study results," "offer," and "sharing." NIH should also define "plain language," "accessible," and "reasonable effort." NIH should explain how the policy applies to secondary research, repositories and registries, studies using previously collected data, cluster-randomized and pragmatic studies, platform trials, studies that close early, minimal-risk behavioral research, and research in which direct contact with participants is no longer feasible. The policy should also clarify responsibilities among principal investigators, coordinating centers, participating sites, data repositories, and award recipients in multisite research.

**Preserve a clear distinction between aggregate findings and individual results -** NIH should state explicitly that this policy concerns aggregate study findings and does not, by itself, require the return of individual research results, incidental findings, diagnoses, or clinical recommendations. Summary communications should explain that aggregate findings may not apply to an individual participant and should identify appropriate points of contact for questions. This distinction matters especially in psychological and behavioral research, where participants might otherwise misinterpret group-level associations, screening measures, or exploratory findings as individualized clinical assessments. Wong et al. (2018) also noted that individual results may vary in clinical utility and raise questions about interpretation and use; NIH should avoid letting guidance on aggregate summaries imply clinical actionability or individualized benefit.

**Establish realistic, risk-based timelines -** APA supports timely communication but urges NIH to recognize that data cleaning, harmonization, analysis, interpretation, and quality review may extend beyond the end of an award period, particularly for longitudinal, multisite, mixed-methods, and complex behavioral studies. The final policy should allow a brief status update when results are not yet dependable and let the final summary follow once analyses are complete. NIH should, where feasible, align timelines with ClinicalTrials.gov and other applicable requirements to avoid conflicting obligations and premature dissemination.

**Provide funding and treat communication as an allowable, reviewable research cost** - High-quality participant communication requires expertise, translation, accessibility services, secure delivery systems, community engagement, and staff time. Logistical constraints and limited resources substantially affect whether investigators share results in practice, and researchers have specifically identified a need for training, time, and assistance in preparing participant-centered messages (Bagita-Vangana et al., 2025; Long et al., 2019; Melvin et al., 2020). A rights-informed approach also requires adequately resourced partnerships with participants and communities throughout the study, including facilitated discussion, relationship-building, co-development, and reciprocal engagement rather than one-way dissemination (George et al., 2023).

NIH should direct applicants to include these activities in study plans and budgets, recognize them as allowable research costs, and permit administrative supplements or other transition support for active

awards that did not anticipate the requirement. Peer review should assess whether the proposed resources are appropriate without using the communication plan as a proxy for scientific impact or disadvantaging less-resourced institutions.

**Use proportionate oversight and a phased implementation** - NIH should assess whether investigators made a documented, good-faith offer of appropriate summary results—not whether every participant received, opened, or understood the communication. At the same time, given the limited evidence from actual dissemination studies, NIH should evaluate implementation based on reach, comprehension, usefulness, equity, participant satisfaction, delivery methods, and whether participants had a meaningful opportunity to discuss, interpret, and use the findings (George et al., 2023; Idnay et al., 2025).



Consistent with Wong et al.'s (2018) call for evidence on what results should be returned, when they should be returned, and how they should be communicated, NIH should use these evaluations to refine its guidance and identify effective practices. The agency should issue model language, templates, implementation tools, and examples across research designs; allow a reasonable transition period; and use corrective action before punitive enforcement.

NIH should also provide shared services or supplemental support for small studies, early-stage investigators, community-based organizations, and under-resourced institutions. The agency should monitor whether summary quality, delivery rates, or participant access differs by institution type, study population, language, disability, or digital access. Without funding and equity monitoring, a universal requirement could produce formal compliance while widening disparities in who receives understandable and usable results.

NIH should coordinate requirements with ClinicalTrials.gov, the NIH Public Access Policy, the Data Management and Sharing Policy, and relevant FDA obligations so that investigators can reuse accurate source content and avoid duplicative reporting. Central NIH resources could include model language for consent forms, sample summaries, readability and accessibility tools, translation guidance, privacy safeguards, and decision frameworks for exceptions.

**Protect privacy and avoid unintended re-identification** - Even aggregate findings may create privacy risks in small samples, rare-condition studies, geographically concentrated research, or studies involving stigmatized experiences or sensitive behavioral data. NIH should permit aggregation, delayed release, omission of identifying details, or an exception when necessary to protect participants and communities. Exceptions should also be available when sharing would create a meaningful risk of harm, conflict with the law, or be impracticable, with clear criteria, prompt review, and an opportunity for reconsideration. Guidance should address secure contact practices, undeliverable communications, changes in contact information, and retention of participants' communication preferences.

**Establish best practices for researchers -** NIH should provide adaptable templates, checklists, examples, and minimum quality criteria rather than impose a single format. At a minimum, every summary should state why the study was conducted, who participated in aggregate terms, what was done, the principal results (including null or unfavorable results), important safety findings, major limitations, what the findings do and do not mean, and where participants can find additional information. This content standard responds directly to evidence that return practices are inconsistent and underdeveloped (Idnay et al., 2025).

Summaries should use descriptive headings, short sentences, visual displays where they aid comprehension, translated versions where needed, and a contact route for questions. When feasible, materials should be reviewed by representatives of the intended audience or undergo a comparable user-testing process. Carr et al. (2025) found that the seven systems identified in their review commonly used multiple delivery modes and combined text with visual displays, but rarely incorporated accessibility features or adequately documented anonymization. NIH guidance should therefore require explicit accessibility and privacy checks covering disability access, language access, identity protection, secure delivery, data retention, and governance.

NIH should clarify the appropriate roles of investigators, institutional review boards, communications specialists, community partners, and institutions. Review should focus on accuracy, participant protection, and consistency with consent. It should not create an unnecessary publication-style approval process (Long et al., 2019; Melvin et al., 2020).

In conclusion, NIH's draft policy is a major step toward making the return of summary-level results a routine element of respectful and trustworthy clinical research. The literature shows broad participant expectations, strong ethical support, inconsistent implementation, and recurring barriers related to resources, logistics, communication capacity, accessibility, and institutional guidance (Bagita-Vangana et al., 2025; Idnay et al., 2025; Long et al., 2019; Melvin et al., 2020). However, important evidence gaps remain.

APA urges NIH to finalize a policy that makes offering summary-level study results a standard part of respectful, transparent research. To ensure that the policy advances participant trust and understanding without creating unintended burdens or inequities, NIH should preserve flexibility across research contexts, provide realistic timelines and adequate resources, protect privacy, and support meaningful participant and community engagement. APA also encourages NIH to pair implementation with practical guidance, a reasonable transition period, and ongoing evaluation so that the policy can evolve as the evidence base grows.

APA appreciates NIH's consideration of these recommendations and welcomes continued collaboration to advance participant-centered research practices. Please do not hesitate to contact Angela L. Sharpe, MG, Senior Director, Congressional & Federal Relations (asharpe@apa.org), with any questions.

Sincerely,

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