Jay Bhattacharya, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

October 26, 2026

Re: Request for Information on a Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants (Notice Number: NOT-OD-26-113)

Dear Dr. Bhattacharya,

The Alzheimer's Association and the Alzheimer's Impact Movement (AIM) appreciate the opportunity to comment on the Draft National Institutes of Health (NIH) Policy on Sharing Summary Level Study Results with Clinical Research Participants.

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support, and research. The Alzheimer's Impact Movement, a separately incorporated advocacy affiliate, is a nonpartisan, nonprofit organization and works to make Alzheimer's a national priority.

Today there are an estimated 8.6 million Americans with the biomarkers of Alzheimer's disease and symptoms, including 4.4 million Americans with dementia due to Alzheimer's and 4.2 million with mild cognitive impairment (MCI) due to Alzheimer's.[1] Research into Alzheimer's and related dementias (ADRD) depends on the willingness of these individuals and their families to take part in studies. The disease does not affect all Americans equally: Black older Americans are approximately twice as likely, and Hispanic Americans about 1.5 times as likely, to develop Alzheimer's or other dementias, and it also disproportionately affects women. Rural Americans, among others, also remain underrepresented in Alzheimer's research.[2] Understanding the disease across the populations it affects, and sustaining their participation in research, is fundamental to measuring disease burden accurately and developing treatments that work for all patients.

The Alzheimer's Association and AIM support NIH's goal of making research results accessible to research participants. Sharing results with participants honors their contribution to research, and we welcome NIH's recognition that doing so is integral to respectful, participant-centered research. The Association has also led work directly relevant to this policy. The Participant FIRST (Participant Follow-Up Improvement in Research Studies and Trials) Work Group, a multidisciplinary group that included research participants and study partners, researchers, industry, patient advocacy organizations, and representatives from NIH, developed published recommendations on communicating study results to participants and their study partners, which we draw on throughout these comments. The Alzheimer's Association applies this guidance in practice, incorporating these expectations into our own research grant

[1] Alzheimer's Association. (2026). *2026 Alzheimer's Disease Facts and Figures.*
[2] Ibid.

agreements. We offer the following input to help the policy work for participants living with Alzheimer's and other dementias, those at risk, and their care partners.

Section 1: Draft Policy Components

The draft policy requires that participants be offered summary level study results. This requirement centers on the participant receiving results directly, and in ADRD research that assumption often does not hold. Participants may enroll while they have capacity to consent but lose the ability to receive or understand results over the course of a study, or may rely on a legally authorized representative as their condition progresses, and some may no longer be living when results become available. In ADRD research, study partners are rarely bystanders. They are often essential to a participant's involvement, invest their own time and effort over the course of a study, and have a real stake in what it found, which is why the Participant FIRST recommendations treat study partners as recipients of results alongside participants. We therefore urge NIH to address who receives results in these circumstances and to expressly permit sharing with care partners and legally authorized representatives, with the participant's preferences captured at consent.

Additionally, results must be shared no later than one year after the primary completion date. In a progressive disease, a year is significant, and a participant's circumstances can change substantially within that window. We urge NIH to ensure the policy provides for timely sharing with the participant and, where appropriate, their care partner or representative, when circumstances have changed.

The policy provides two exceptions to sharing: a pre-enrollment exception where sharing is "justifiably not appropriate," and a provision for unforeseen circumstances that later make sharing impossible. NIH does not define what qualifies as "justifiably not appropriate." We urge NIH to define this standard narrowly so that it does not become a routine opt-out, particularly for studies enrolling people with cognitive impairment, where a broad exception could too easily justify not sharing at all. Where sharing becomes impossible, we support informing participants of those reasons and urge that this communication also be provided in plain language and, where appropriate, to care partners or representatives.

By design, the policy covers aggregate results and excludes individual results. In ADRD research, this line is not always clear, as aggregate findings can carry implications that participants read as personal. We urge NIH to account for this where summary results may be received as individually meaningful.

Finally, under the draft policy, failure to comply may provide a basis for enforcement actions, including additional special terms and conditions or termination, and may affect future funding decisions for the recipient institution. We request that NIH provide additional detail on how these enforcement provisions would apply to the results-sharing requirement, including how good-faith efforts to reach participants would be considered and what circumstances would trigger enforcement. Greater clarity would help investigators and institutions understand their obligations and plan accordingly.

Section 2: Proposed Supplemental Guidance

We appreciate that NIH has already sought input from participants and other stakeholders in developing this policy, and we encourage NIH to continue drawing on the perspectives of people with lived experience, including those gathered through its prior engagement, as it finalizes the policy and supplemental guidance. We urge NIH to issue supplemental guidance and offer the following input on the three proposed topics: participant preferences and experiences, best practices for researchers, and implementation needs.

I. Participant Preferences and Experiences

1. What participants find valuable when receiving summary level study results and what, in addition to the final result(s), they find relevant to be shared.

When participants receive summary results, what they value most is knowing their contribution mattered. Members of the Alzheimer's Association's Early-Stage Advisory Group, individuals living in the early stage of Alzheimer's and other dementias, emphasized that knowing their contribution mattered and understanding what the findings mean for them are both valued, underscoring the importance of helping participants understand what summary results do, and do not, tell them as individuals. Participants also value results for how they can be shared more broadly: as the Association's work on participant involvement describes, participants report that receiving results allows them to share what they have learned within their communities, which can in turn encourage others to take part in research.[3] Beyond the headline finding, a useful summary conveys what the study set out to learn, what it found overall, what the results mean for people like them, and, where known, what the findings may mean for future research or care. In ADRD research, summaries should be meaningful to both the participant and the care partner who often supports their involvement.

2. Participants' preferred method(s) for receiving summary level study results and expectations for what information should be communicated.

How results reach participants matters as much as what they contain. In ADRD research in particular, cognitive impairment and the central role of care partners shape how results should be delivered. The Association's work on participant involvement notes that cognitive impairment may call for adaptations such as one-on-one or small-group communication, and that written materials are most useful when provided both before and after any conversation.[4] Participants should be able to receive results through multiple channels and formats suited to their needs, including accessible print and, for people with cognitive impairment, the option for a care partner to receive results alongside the participant. Advisory group members described a conversation with the research team, one that includes the care partner, as the most valuable way to receive results. They also suggested the option to share summary results with a participant's own clinician, which may help participants, particularly those with cognitive impairment, understand the findings. A written plain-language summary, paired with the opportunity to ask questions of that team, can reinforce such a conversation and give participants something to return to. Throughout, participants should be told plainly what the study found, what it does and does not mean for them individually, and where to turn with questions, and both participants and study partners should be contacted promptly once results are available rather than through a single passive notification.[5]

3. Participant/family/community concerns about receiving summary level study results, and how they could be addressed.

A central concern, which NIH acknowledges, is that results may raise questions the study cannot answer. Participants may also worry about how population-level findings relate to their own health or risk. In ADRD research, families may find results emotionally significant, particularly when findings arrive long

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[3] Walter S, McArdle RÍ, Largent EA, et al. Public and participant involvement as a pathway to inclusive dementia research. *Alzheimer's & Dementia.* 2025;21:e14350.
[4] Ibid.
[5] Largent EA, Walter S, Childs N, et al. Putting participants and study partners FIRST when clinical trials end early. *Alzheimer's & Dementia.* 2022;18(12):2736-2746; Walter S, Largent EA, Edelmayer RM. Supporting participants and study partners when trials end as planned. *Alzheimer's & Dementia.* 2023;19:1590-1591.

after a study has ended. Several Early-Stage Advisory Group members suggested that interim updates during a study, especially where final results may not be available until well after it concludes, would help address this concern. NIH can further address these concerns by framing results in plain language, offering a point of contact for follow-up questions, and providing referral to appropriate support and information resources.

II. Best Practices for Researchers

4. Effective, low burden approaches for developing summary level study results that are in plain language and culturally and contextually appropriate.

Developing plain-language summaries does not need to place a new burden on each study team. NIH should point researchers to established health literacy resources and provide model templates, rather than expect each team to build an approach from scratch. Materials should be developed with input from the communities a study enrolls so that they are culturally and contextually appropriate. The Association's recommendations on involving participants in research emphasize communicating without jargon or acronyms and defining terms in partnership with the community, principles that apply directly to preparing summary results.[6] The Alzheimer's Association would welcome the opportunity to serve as a resource on communicating research findings to people living with dementia and their care partners.

5. Key elements that are most important to include, helpful formats, and strategies to promote understanding.

A useful summary conveys what the study set out to learn, what it found overall, what the findings do and do not mean for an individual participant, and what comes next. For many studies, the most important element is a clear statement distinguishing aggregate findings from individual results, so that participants do not read population-level results as a personal prediction. Plain language, short sections, visual aids where helpful, and a named contact for questions all promote understanding. Findings should be summarized for participants and their communities in accessible form, and prepared answers to frequently asked questions, along with a personalized closeout conversation, further support understanding.[7]

6. Considerations for identifying which results should be returned (e.g., primary vs. secondary results) including for specific study populations, study designs, and longitudinal studies.

Which results are returned, and which are not, should be determined through a clear and intentional plan set out in the study design, rather than left to ad hoc decisions, and communicated transparently to participants at enrollment. In developing that plan, applicants should consider which categories of results (primary, secondary, or incidental) will be returned, and weigh the validity of each result, its value to participants, and the feasibility of returning it. We encourage NIH to ask applicants to specify, as part of their study plan, what information will and will not be shared with participants and the reasoning for those choices; how the return of research results will be addressed in consent discussions at enrollment; and when and how participants will receive results over the course of a study, including in longitudinal studies. Materials should make clear that these are research results, not clinical guidance, a diagnosis, or individualized medical advice. The National Academies of Sciences, Engineering, and Medicine has published a consensus framework that approaches the return of results as a deliberate, case-by-case decision, weighing the value of a result to the participant, its validity and quality, and the feasibility of returning it. The framework also emphasizes transparent decision-making, communication with

[6] Walter et al., "Public and participant involvement."
[7] Walter et al., "Supporting participants and study partners."

participants, and adequate supporting infrastructure.[8] Documented practices across the NIH-funded Alzheimer's Disease Research Centers further illustrate how these principles are applied.[9] Beyond the mechanics of what to return, the return of results also shares a broader purpose. The Association's work on participant involvement speaks to the return of results as a way to improve inclusiveness in research: because Alzheimer's disproportionately affects some communities, sharing findings back with participants helps build the trust and partnership needed to engage and retain those most affected in ADRD research.[10]

7. Situations where sharing summary level study results is not possible or desirable.

The Association and AIM recognize that sharing results will not be appropriate for every study or every participant, and the policy's exception process should account for that. Because the "justifiably not appropriate" exception is requested before the first participant enrolls and applies to the study as a whole, it should be defined clearly and narrowly so that studies do not waive sharing routinely. Any exception should be documented and justified.

The policy's unforeseen-circumstances provision addresses situations where sharing results becomes impossible, but studies may also end early while still yielding results, or raising questions, that matter to participants. The Participant FIRST recommendations address studies that end early, advising that the possibility of early stoppage be covered in the communication plan and during informed consent, and that results still be shared with participants and study partners even when a study ends before plan.[11] We encourage NIH to ensure participants are informed in these circumstances, and to distinguish genuine constraints on the timing of disclosure from circumstances that would excuse sharing altogether.

8. Considerations for sharing summary level study results with individuals other than the research participants, such as parents/guardians/caregivers of participants.

In ADRD research, care partners and legally authorized representatives are often central to a participant's involvement and are frequently the appropriate recipients of results. This is consistent with a principle long embedded in the Association's Dementia Care Practice Recommendations, which treat care partners as integral members of the care team and hold that a person's preferences and wishes should be honored in all phases of the disease, even when proxy decision making is required.[12] Members of our Early-Stage Advisory Group likewise supported including the care partner in communications, where the participant has authorized that disclosure. NIH should expressly permit and guide sharing results with care partners and legally authorized representatives, with the participant's preferences and authorization captured in advance, ideally during informed consent, including whom the participant wishes to receive results if they later cannot. For studies enrolling people with cognitive impairment, this should be a core element of study design, not an exceptional case.

III. Implementation Needs

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[8] National Academies of Sciences, Engineering, and Medicine. *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm.* Washington, DC: The National Academies Press; 2018.
[9] Ibid.; Rahman-Filipiak A, Chin NA, Kohl H, et al. Return of research results across the Alzheimer's Disease Research Centers network. *Alzheimer's & Dementia.* 2025;21(6):e70418.
[10] Walter et al., "Public and participant involvement."
[11] Largent et al., "Putting participants and study partners FIRST."
[12] Fazio S, Pace D, Maslow K, Zimmerman S, Kallmyer B. Alzheimer's Association Dementia Care Practice Recommendations. The Gerontologist. 2018;58(S1).

9. Types of activities required to share summary level study results to participants and the anticipated costs associated with those activities for different kinds of studies.

Sharing results with participants involves real and legitimate costs. Developing accessible, plain-language summaries and maintaining contact with participants and care partners over long study timelines takes effort, particularly in longitudinal ADRD research where follow-up may span years. NIH can reduce this burden substantially through shared tools and templates, as discussed in our response to question 10. Resources and funding for orderly study closeout should be built into the study budget from the outset, as should the costs of communicating results, which NIH could reflect in its implementation guidance.[13]

10. Information on resources, infrastructure and other non-monetary supports that would help prospectively plan for and implement the requirement to share summary level study results in a way that is understandable and meaningful to all clinical research participants in a study.

The most effective support NIH could provide would be shared infrastructure that study teams can draw on rather than build themselves. NIH-provided templates, plain-language toolkits, and model informed-consent language for capturing results-sharing preferences, including designation of a care partner or legally authorized representative to receive results, would lower burden and improve consistency across studies. Centralized guidance and examples would be especially valuable for smaller study teams. Involving people with lived experience of dementia in developing and testing these materials helps ensure they are clear and meaningful. Researchers should also collaborate with patient advocacy organizations to support participants and study partners, a role the Alzheimer's Association is well positioned to fill.[14] The Alzheimer's Association would welcome the opportunity to share perspectives from our Early-Stage Advisory Group, composed of individuals living in the early stage of Alzheimer's and other dementias, to inform that work.

11. Any existing methods, tools, best practices, or guiding principles that enable sharing summary level study results more effectively.

As noted above, the Participant FIRST Work Group, convened by the Alzheimer's Association, developed recommendations directly relevant to this policy. Published in *Alzheimer's & Dementia*, they span the pre-trial, mid-trial, and post-trial periods and include allocating resources for orderly study closeout, maintaining participant and study-partner contact information over the course of a study, contacting participants promptly once results are available, personally informing them of results, offering a personalized closeout conversation, preparing answers to frequently asked questions, and ensuring full results are shared with both participants and study partners.[15]

A broader body of guidance and practical experience on returning results to participants is also available for NIH to build on, including the National Academies framework referenced above, staged participant-centered disclosure processes developed by clinical and research teams, and guidance on involving participants in research as a means of making it more inclusive.[16] A 2024 survey of the NIH-funded

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[13] Largent et al., "Putting participants and study partners FIRST"; Walter et al., "Supporting participants and study partners."
[14] Largent et al., "Putting participants and study partners FIRST"; Walter et al., "Supporting participants and study partners."
[15] Largent et al., "Putting participants and study partners FIRST"; Walter et al., "Supporting participants and study partners"
[16] National Academies, *Returning Individual Research Results to Participants*; Walter et al., "Public and participant involvement."

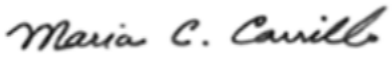
Alzheimer's Disease Research Centers found that returning results to participants, including sensitive individual findings such as biomarker results, is both feasible and increasingly common. Even these more detailed disclosures are typically completed in about 30 minutes and follow a consistent structure of pre-disclosure education, clear communication, and follow-up, with results shared with participants and, at their discretion, a support person.[17] Notably, the most common barrier these centers reported was that returning results had not been planned into the study from the outset, reinforcing the value of addressing results-sharing in study design. Large longitudinal studies, including the U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk (U.S. POINTER), have also launched return-of-results programs.[18]

Together with the Participant FIRST recommendations, this body of work offers NIH a foundation of real-world experience. The Alzheimer's Association would welcome the opportunity to help identify and adapt these resources for the ADRD community.

Thank you for the opportunity to comment. The Alzheimer's Association and AIM would be glad to serve as a resource to NIH as it considers these important issues and how they relate to individuals living with Alzheimer's and related dementias. Please contact Laura Thornhill, Director, Regulatory Affairs, at 202-638-7042 or lthornhill@alz-aim.org if you have questions or if we can be of additional assistance.

Sincerely,





Robert Egge
Chief Public Policy Officer, Alzheimer's Association
President, Alzheimer's Impact Movement

Maria C. Carrillo, Ph.D.
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[17] Rahman-Filipiak et al., "Return of Research Results."
[18] Ibid.