October 26, 2026

RE: Notice No. NOT-OD-26-113. Request for Information: Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants

Dear Sir or Madam,

On behalf of the Pediatric Inclusion Alliance (PIA), we are pleased to submit comments on NIH's Request for Information on "**Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants.**" PIA strongly supports the proposed goal of strengthening transparency, trust, and participant engagement. Furthermore, we appreciate the opportunity to provide stakeholder feedback on the benefits of sharing summary level study results with clinical research participants, including how this can empower participants and their caregivers throughout their health journey. Given the unique role of parents, caregivers, and pediatric participants in clinical research, PIA recommends that NIH incorporate pediatric-specific considerations throughout the final policy and any supplemental implementation guidance. This effort would help to ground the policy proposal in the realities of pediatrics patients, making it both more effective and applicable.

About the Pediatric Inclusion Alliance

The Pediatric Inclusion Alliance ("PIA" or "Alliance") is devoted to full, active collaboration among all stakeholders committed to achieving earlier inclusion of children in clinical trials across all diseases and conditions without compromising safety. For far too long, children have had to wait years for access to safe, effective therapies, often already approved for adult populations. These therapies might well have been even more effective for younger patients if administered at the best time for them.

By combining a deep understanding of the needs of pediatric patients and their families, technical expertise, real-world experience in medical research and therapy development,

knowledge of regulatory guidance and processes, and public policy experience, the Alliance is a united collaborative of stakeholder groups committed to ensuring that children have the earliest opportunity to access safe and effective therapies when those therapies are most likely to have maximum benefit to them. This is especially true for early onset genetic disorders, the affected populations for which could benefit profoundly from inclusion of children in clinical trials earlier, at the point of maximum impact for them.

General Considerations for Early Pediatric Inclusion

As NIH has identified,[1] responsible sharing of clinical trial data is both in the interest to individual participants as well as the public writ large. Contributions made by clinical trial participants to scientific knowledge can benefit future patients and society as a whole. This is particularly true for rare pediatric disease populations where there may be limited prior research due to small patient populations.

Providing summaries of trial results to participants presents an opportunity to reaffirm participant and parental value, educate adolescent participants and their caregivers about clinical research, and foster trust in clinical research as a whole. NIH should leverage already developed "return of research results" best practices from researchers in the field, which includes practices like leaning on parental preferences, maximizing participant autonomy and choice, and establishing a process where disclosure will not lead to harm, mitigating for harm risks should they occur.[2] Implementation needs for pediatric studies as it relates to sharing summary-level research results may require additional resources for caregiver communication, adolescent-specific materials, and long-term participant engagement efforts.

Feedback on Proposed Supplemental Guidance

I. Participant Preferences and Experiences

PIA supports NIH's goal of ensuring that participants receive meaningful, understandable summaries of the clinical trials to which they contributed. We also appreciate that this policy will be applicable to all NIH-supported clinical research, including but not limited to clinical trials. Based on our members' direct experiences, we recommend that supplemental guidance should establish a minimum content standard while allowing the format and level of detail to be adapted to the study population. At a minimum, summaries should do the following:

- explain the study purpose and why participants were enrolled;

[1] https://www.ncbi.nlm.nih.gov/books/NBK285993/

[2] Guidelines for return of research results from pediatric genomic studies: deliberations of the Boston Children's Hospital Gene Partnership Informed Cohort Oversight Board

- state the study objectives and whether they were met;
- describe key efficacy, safety, and tolerability findings;
- identify important limitations and remaining uncertainties; and
- explain what was learned even when the study did not meet its primary endpoint.

NIH should also encourage investigators to ask participants during enrollment whether and how they wish to receive summary-level results, while making clear that these preferences may be updated. Offering at least two practical communication options, based on the study population and available resources can support choice without creating an unmanageable burden for clinical research programs. We suggest the following mechanisms for communication:

- secure electronic communications or participant portals;
- written plain-language summaries;
- virtual group study update sessions; and
- dissemination through trusted patient advocacy organizations or community networks.

PIA also encourages NIH to provide additional guidance regarding the timing of returning summary-level study results to participants. Participants should be informed before enrollment about the anticipated timeline for receiving summary-level results and notified if that timeline changes. Participants should receive study findings in a timely manner after results are available, particularly in rare disease and pediatric research where study opportunities may be limited and future research decisions may depend on emerging information. At the same time, PIA recognizes that appropriate timelines may vary based on factors such as study size and length, the number and type of endpoints being analyzed, statistical considerations, and publication or regulatory considerations. Rather than establishing a single universal deadline, NIH could consider developing a rubric that categorizes studies and outlines appropriate result-sharing timelines based on study characteristics. This approach may help promote consistency while allowing flexibility for different types of clinical research.

For pediatric studies, a single communication approach may not meet the needs of every participant and their families. NIH should encourage researchers to develop adaptable, age- and developmentally appropriate materials that can be used with children, adolescents, parents, guardians, and caregivers. These materials should be supportive to parents' and guardians' role in deciding how results are shared with their children. Guidance should also recognize that preferences can change over time, especially in longitudinal studies when a child matures, gains decision-making capacity, or reaches the age of majority. Research involving adolescents and parents has found value in both independent and shared decision-making, supporting an approach that gives adolescents a meaningful voice while recognizing the

responsibilities of parents and guardians.[3] To support possible follow-up of summary-level research results to participants, NIH should consider recommending clinical trial programs identify a clear point of contact or resource for follow-up questions within the scope of the study. In pediatric research, investigators may anticipate that participants and their families may interpret the same information differently. Communication plans should be designed to address those distinct informational needs through practical, scalable approaches without excluding the young person from an appropriate age discussion.

II. Best Practices for Researchers

We appreciate NIH's attention to developing best practices for researchers who will be required to provide summary level results for participants. To improve consistency and reduce implementation burden for researchers, NIH can provide practical, adaptable tools rather than asking each research team to develop materials from the ground up. A modifiable, core guidance may include the following:

- a standard summary template,
- model consent and assent language describing result-sharing expectations,
- examples of effective participant communications, and
- readability and health-literacy guidance.

Existing resources from organizations with experience in aggregate-results communication can serve as a foundation and help NIH avoid duplicating tools already in use[4].

For pediatric studies, summaries should additionally explain the relevance of the findings to children and families, identify developmental considerations when applicable, and describe long-term follow-up findings or plans. PIA recommends a strong presumption that primary outcomes, key secondary outcomes, important safety findings, and findings that materially advance understanding of the disease, condition, or treatment should be shared. In pediatric and rare disease research, clinically meaningful secondary findings may be especially important because families often participate not only to evaluate a specific intervention but also to advance knowledge in areas with limited evidence or treatment options.
Researchers should also consider how best to ensure these summaries are shared with patients' primary care physicians, when feasible. Care is often fragmented between specialists and primary care providers, particularly when they operate in different health systems.

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[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC6146016/
[4] https://publications.aap.org/pediatrics/article/152/6/e2023063436/194588/Sharing-Pediatric-Trial-Results-With-Youth-and?autologincheck=redirected

Providing these summaries to primary care physicians can help bridge those gaps, improve care coordination, and support greater continuity of care across the patient's healthcare journey.

III. Implementation Needs

We appreciate NIH's consideration of potential administrative burden in sharing summary-level results to clinical research participants for clinical trial programs, particularly those who cater to specialized populations, like pediatrics. To support the implementation needs of these programs, we recommend NIH recognize the following activities as allowable and necessary research costs in order to support researchers providing summary-level results:

- drafting and testing plain-language, developmentally appropriate materials,
- health-literacy review,
- translation and accessibility services,
- graphic design,
- participant outreach and tracking,
- community engagement, and
- information technology infrastructure.

To support consistent implementation across institutions, NIH should develop or curate a practical infrastructure package that includes model templates, investigator training, IRB implementation resources, repositories of sample summaries, and examples tailored to pediatric and other types of studies. NIH should leverage existing methods and best practices from patient advocacy organizations, academic research centers, and clinical trial networks. These groups can help ensure that guidance is realistic and grounded in the experiences of how families receive and use information.

PIA further recommends a dedicated pediatric supplement to the final guidance. A pediatric-focused resource should address developmentally appropriate communication, assent and consent, parent and caregiver engagement, adolescent involvement, transition to adulthood, and communication of long-term safety and efficacy findings. Streamlining these issues in one resource would provide researchers and IRBs with a consistent framework while still allowing study-specific adaptation.

Conclusion

PIA strongly supports NIH's efforts to require summary-level study results be shared with clinical research participants. For pediatric populations, returning study results strengthens trust, demonstrates respect for participants and families, and reinforces the principle that research participants, including children, are partners in the research process. NIH should

ensure that implementation guidance incorporates the unique needs of children, adolescents, parents, guardians, and caregivers while providing researchers with clear, practical tools to facilitate meaningful and sustainable participant engagement.

The Alliance appreciates NIH's leadership on this important issue and looks forward to continued engagement as the Agency finalizes this guidance and advances policies that help ensure children participate in clinical research with the ultimate goal of gaining earlier access to safe and effective therapies at the point of maximum impact for them. If you have any questions or would like to discuss this further, please contact Sara Singleton at Sara.Singleton@Leavittpartners.com.

Sincerely,

Ron Bartek

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Convenor, Pediatric Inclusion Alliance

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