



# American Society of Hematology

Helping hematologists conquer blood diseases worldwide

## 2026

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October 23, 2026

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Submitted electronically via <https://www.regulations.gov>

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

Dear Dr. Jorgenson:

On behalf of the American Society of Hematology (ASH), we appreciate the opportunity to provide feedback on the National Institutes of Health (NIH)'s draft policy on sharing summary level study results with clinical research participants.

ASH represents more than 18,000 clinicians and scientists committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematologic (non-malignant) conditions like sickle cell disease (SCD). In addition, hematologists are pioneers in the field of medicine and continue to be innovators in areas such as stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

Overall, ASH supports NIH's goal of sharing summary-level study results with research participants, recognizing this as an important responsibility of clinical investigators. In fact, disseminating study results to individuals who participated in the trial is a point that is emphasized in the [ASH Toolkit for Clinical Trial Sponsors](#). As NIH stated, sharing results in an honest, accessible, and thoughtful manner also recognizes participants as partners in research. When done well, returning results may also strengthen participant trust, improve understanding of research, and support future engagement in clinical studies.

ASH conducted a survey of our members to receive input on this proposal and offers the following feedback on the draft policy and proposed supplemental guidance for NIH's consideration.

### Section 1: Draft Policy Components (Purpose, Definitions, Scope, Requirements, Compliance and Enforcement)

While ASH supports the draft policy intent, we offer several suggestions to promote the delivery of clear, meaningful information to research participants without imposing undue burdens on investigators and research institutions.

## Administrative Burden and Resources

Without additional resources to support the return of study results, the proposed requirements may impose significant administrative and financial burdens on investigators and research institutions. Activities such as developing plain-language summaries, translating study results that allow for accessibility, incorporating patient or community input, maintaining participant contact information, distributing results, and responding to questions could substantially increase costs. Maintaining contact is particularly challenging in large studies involving thousands of participants. Additional support from individuals trained to communicate scientific findings to lay audiences may also be necessary. The additional activities associated with sharing study results with participants should be planned and budgeted for at the outset of a study rather than treated as additional responsibilities at its conclusion. We encourage NIH to provide implementation workshops, model workflows, and examples of participant-facing summaries that investigators and sponsors can adapt for different study designs and participant populations.

To further minimize administrative burden, ASH experts recommend clinical trial sponsors establish a standardized process for collecting participants' email addresses at enrollment for the purpose of sharing study results electronically. If a participant does not have an email address, alternative contact information must be collected and stored for future use. Confirmation that results have been sent or attempts to contact the trial participants should serve as sufficient documentation of compliance, rather than requiring additional verification, thereby reducing unnecessary administrative burden on investigators and research institutions. The [ASH Toolkit for Clinical Trial Sponsors](#) encourages sponsors to work with healthcare providers and patient advocacy groups to help share information with study participants. This approach could offer another pathway to reduce the administrative burden on the sponsor.

## Exceptions to Reporting Requirements

ASH's experts generally agree that exceptions to reporting trial results may be warranted to protect participant safety and privacy, particularly in studies with small sample sizes or risks of revealing an individual participant's identity from de-identified data. However, exceptions should be limited and clearly justified. It would also be important for participants to know prior to enrollment whether they can expect to receive results. More importantly, ASH believes that complicated, negative, or inconclusive findings should not justify withholding results from trial participants. Even when findings of a clinical trial are inconclusive, participants should understand what was learned, what remains unknown, and how the trial findings may inform future research.

## Timeline for Returning Results

Generally, ASH considers the requirement to share clinical trial results within one year of the primary completion date appropriate. However, given that data analysis can often take more than a year to complete and generating a meaningful summary of the results can take additional time, we encourage NIH to provide flexibility for reporting timelines. Trial participants should also be informed about this timeline at the outset, and if results are not yet available, participants should receive timely updates rather than waiting for years without any communication. ASH also notes that further clarification is needed regarding the use of the end of the period of performance as the reporting deadline for other types of clinical research. In these cases, sharing summary-level results at the same time that a manuscript or oral presentation is prepared may be more reasonable and less burdensome for researchers.

## Section 2: Proposed Supplemental Guidance

ASH strongly recommends that NIH make expectations for clinical investigators clear, provide a basic framework or template to decrease administrative burden, and develop guidance that promotes the provision of information about clinical trial results that is clear and understandable. At the same time, ASH recommends that researchers be given sufficient flexibility in generating summary level results because every study and participant population is different. Additionally, NIH must understand that data points, and scientific findings considered by researchers as important often vary as compared with what participants consider important. ASH recommends that NIH develop guidance with significant input from the patient/clinical research participant communities.

In general, trial summaries should explain why the study was done, what researchers learned, why it matters, what the study limitations were, what remains unknown, and what happens following the completion of the trial. The goal should not just be providing clinical trial information. It should create an understanding of the trial and its results. For instance, "plain language" should mean more than removing medical or research terminology; "easy to read" does not necessarily mean the patient understands why the information matters.

ASH recommends that clinical trial results use varying formats, including written summaries, FAQs, visuals, videos, and opportunities for study participants to ask questions.

In summary, ASH supports the concept of sharing clinical trial results, but we recommend minimizing burden on investigators and research institutions. We recommend that NIH:

- ensure that associated costs and burden can be considered and budgeted for at the beginning of the research;
- establish limited, clearly justified exceptions for safety and privacy concerns;
- clarify reporting timelines and provide flexibility when additional time is needed;
- provide clear written guidance, including communication tools, translation resources, and guidance on maintaining participant contact information, as well as standardized but flexible templates, and implementation workshops; and
- involve patients, caregivers, and community representatives in developing communication standards to ensure that returned results are understandable and meaningful to clinical trial participants.

As noted, ASH has been actively considering how best to share summary-level study results with clinical research participants and is developing resources to support the hematology community in this area. ASH would welcome the opportunity to engage with NIH to help advance these efforts. For example, the [ASH Toolkit for Clinical Trial Sponsors](#) is one resource NIH could leverage.

Should NIH have any questions or need clarification on the comments, please contact Stephanie Kaplan, ASH Director of Government Relations and Public Health, at [skaplan@hematology.org](mailto:skaplan@hematology.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert Negrin', with a stylized flourish at the end.

Robert Negrin, MD  
President