October 26, 2026

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Submitted electronically

Re: Request for Comment: Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants

Dear Members of the NIH Office of Science Policy:

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), National Advisory Committee on Human Research Protections (NACHRP), and Public Responsibility in Medicine and Research (PRIM&R) respectfully submit this joint comment on the draft *NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants*. We represent Human Research Protection Programs (HRPPs), professionals dedicated to protecting participants in research, and Institutional Review Boards (IRBs).

We agree with the assertion in the request for comment that returning research results to research participants can "help to build trust and communication between researchers and participants, improve participant recruitment and retention rates, enhance clinical research study design and feasibility, and ensure health discoveries are meaningful, accessible, and understandable for patients, clinicians, and participants who may benefit from the research." Sharing summary level results supports participant recruitment and retention advancing enrollment in clinical trials. In general, our organizations support the draft *NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants*. We offer the following comments in the spirit of helping NIH achieve the goals expressed in the proposed policy most efficiently and effectively.

General Comments

Scope. The draft policy appears to require dissemination of summary level study results (SLSR) for all clinical research. In some clinical research, however, participants are unaware of their inclusion in the research, such as studies of medical records that do not involve interaction with research participants. IRBs may approve research, including some clinical trials (e.g., pragmatic clinical trials), with waivers of informed consent. We recommend NIH clarify that direct provision of SLSR is not required when individuals were not informed of their inclusion and direct notification would be infeasible or inappropriate. NIH should establish clear, prospective criteria for these circumstances and permit categorical exceptions or a streamlined approval process for studies meeting those criteria, rather than requiring separate, study-specific exception applications. In such cases, investigators

should be permitted to use appropriate public dissemination channels to share plain-language aggregate findings.

Distinguishing direct return from public dissemination. NIH already requires various forms of public access to NIH-supported research findings; the proposed policy addresses the additional goal of sharing results directly with participants. These are complementary, but distinct responsibilities; the appropriate method of dissemination should reflect the nature of the research and whether direct communication with participants is feasible and appropriate. Because research is intended to develop or contribute to generalizable knowledge, aggregate findings should remain publicly accessible even where individual notification is inappropriate or impracticable. Public posting should be an alternative to direct notification only in the defined circumstances described above, not a universal substitute for communication with participants.

Participant autonomy. We strongly support NIH's position for researchers to offer participants the opportunity to decline to receive SLSR. The policy also should specify when and how participants may record or change their preferences, whether a refusal applies only to study-wide results or also to later updates, and how researchers should honor a request for no further contact. These choices should be communicated in plain language without implying that participants must receive results to remain enrolled.

As currently written, the opt-out framework in the draft policy assumes ongoing contact with a known participant. Thus, we request that further clarifications be provided for the following circumstances:

- When participants may become adults during a study:
    - The expectations for researchers to contact former minors who have reached the age of majority to determine their wishes about receiving SLSR;
    - Whether the parents/guardians who initially consented for the child also should receive the SLSR.
- How to address offering SLSR to loved ones of participants who have passed away before the report has been released.

Premature study termination. We encourage NIH to consider how to address providing SLSR when a study stops early, including research interruptions due to termination of funding. In those cases, we generally support providing participants with a summary of any activities completed and an explanation as to why the research was discontinued. Such an approach could help promote transparency.

Studies with multiple components or stages. The draft policy might more clearly address expectations for dissemination of SLSR when studies have multiple components (e.g., substudies, repositories) or analysis stages, specifically addressing which results should be released and when. A workable policy would identify a triggering event for dissemination, allow a staged summary when different components conclude at different times, and explain how investigators should manage interim findings that could be misleading without sufficient context. NIH also should clearly address who bears responsibility for SLSR communication when a substudy or data repository has a different investigator or sponsor.

IRB role. Several articles and SACHRP recommendations[1] suggest IRBs should be involved in the review of SLSR plans. IRBs appear to have the authority under the Common Rule to determine whether the provision of SLSR that are clinically relevant should be included as part of the informed consent process [45 CFR 46.116(c)(8)]. Further, as part of the criteria for IRB approval, IRBs are required to ensure adequate protection of participant privacy, which could extend to the collection of information needed to track participants to provide SLSR. We encourage NIH, working with OHRP and the FDA, to provide clear guidance about any expectations for IRB review and approval of plans for SLSR provision to discourage IRB mission creep.

From our perspectives, the IRB role related to SLSR dissemination would be limited. Assessing the adequacy of a plan to disseminate SLSR to research participants does not appear to inherently exist within the scope of IRB authority under U.S. federal regulations. Further, with some exceptions noted below, dissemination is an activity unlikely to impact the criteria for IRB approval. We recommend distinguishing IRB review of consent language, privacy risks, and participant-facing contact procedures from approval of every results summary. NIH should clarify that IRB review of plans for results communications is expected only to the extent necessary to fulfill applicable regulatory responsibilities, such as addressing informed consent, participant privacy, or other human subject protection concerns. NIH should avoid creating additional, open-ended IRB review obligations beyond those responsibilities, particularly after study closure.

Dissemination methods. We support institutions and researchers developing dissemination plans that encompass multiple methods. Methods should be tailored to the population enrolled, taking into consideration age, culture, primary language, and accessibility issues.[2] We agree with COGR that the policy should incorporate flexibilities that enable reporters to develop communication strategies that reflect the nature of the trial and are responsive to participant preferences.

ClinicalTrials.gov could serve as one channel to disseminate SLSR. We support COGR's recommendation that NIH work with FDA to consider how SLSR developed under the draft policy can be incorporated into required result reporting in ClinicalTrials.gov to both promote public access to the information contained within that website and potentially eliminate the need to create alternative and potentially duplicative communications channels. Although we support including results in ClinicalTrials.gov, we think this approach as the sole means of dissemination of SLSR would be insufficient and a separate participant-directed communication should still be required. A public posting should complement, not replace, an agreed-upon method of informing participants that results are available. NIH should distinguish the technical act of posting a summary from reasonable efforts to make that information discoverable and understandable, while recognizing that participants may prefer not to be contacted.

Cases where SLSR may be inappropriate. We agree with SACHRP's 2015 recommendations that:

- For studies of illegal or socially stigmatizing behavior such as illegal drug use or sex work,

[1] Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations Regarding Return of General Research Results

[2] Gina M. Sgro, Maureen Maurer, Beth Nguyen, Joanna E. Siegel, Return of aggregate results to study participants: Facilitators, barriers, and recommendations. *Contemporary Clinical Trials Communications*, 33 (2023)https://doi.org/10.1016/j.conctc.2023.101136

providing results to participants might create too great a risk of a breach of confidentiality and subsequent harm.

- The potential for breaches of confidentiality or privacy in small studies with limited numbers of participants where the potential exists for participants to identify themselves and other participants.

We suggest framing these as circumstances warranting a case-specific assessment of confidentiality and potential harm, rather than categorical exclusions based solely on the research topic. Where direct return poses an identifiable risk, NIH should permit de-identified public summaries, intermediary communications, or other approaches that preserve access without revealing an individual's participation.

Cost offsets. As SACHRP[3] notes, the cost of administrative support necessary for the preparation, review, and return of the SLSR could be considerable, whether those activities are performed by employees of the sponsor, researchers, or third parties. Costs include re-writing the information in lay language, any third-party reviews (if required or desired), translation of materials, ensuring materials are accessible, the distribution of the information, and maintaining the contact data of the subjects. We strongly support NIH allowing researchers to budget for creation and dissemination like PCORI[4] does. Alternatively, NIH could provide institution-level support for the centralized creation of resources to support their NIH-funded researchers. To make this expectation feasible, NIH should expressly recognize reasonable dissemination costs as allowable expenses, including personnel time, rendering materials in accessible formats, translation, contact-management systems, and participant questions following release. NIH should also allow use of AI to create, translate, render accessible, or disseminate materials as acceptable costs. The final policy should also address studies that have awards end before results are ready, so that the obligation is not imposed without a practical funding mechanism.

Rollout. While we appreciate the NIH thinking broadly about which research participants receive SLSR, we urge the NIH to consider, similar to a recommendation from COGR[5], a staged rollout of the new policy. Further, we encourage NIH to assess implementation, involving feedback from researchers and IRBs, after each phase to address unanticipated challenges that arise. Beginning the rollout with clinical trials, which already are generally required to post public-facing materials in Clinicaltrials.gov, could make sense as the first phase. We recommend that NIH publish an implementation timetable, sample dissemination plans, plain-language examples, and a proportional compliance framework before the effective date. Evaluation should track not merely whether a summary was produced, but whether participants could access and understand it, whether privacy concerns arose, and what administrative burden was created.

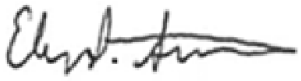
We appreciate the opportunity to comment and welcome the chance to provide additional information to the NIH.

[3] Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations Regarding Return of General Research Results

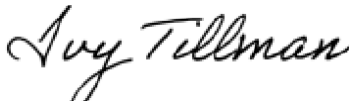
[4] PCORI's Policy on Communicating Study Results to Participants

[5] COGR Comments on Proposed NIH Policy for Sharing Summary Level Study Results with Participants

Respectfully submitted,



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