



October 26, 2026

National Institutes of Health
Office of Science Policy
Bethesda, Maryland

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

Submitted electronically via NIH Office of Science Policy comment form

The National Health Council (NHC) appreciates the opportunity to provide comments on the National Institutes of Health's (NIH's) draft policy on sharing summary level study results with clinical research participants. The NHC supports establishing the expectation that participants will be offered clear, plain-language information about the overall findings of NIH-supported clinical research to which they have contributed. This expectation should be implemented in a manner that respects participants' preferences, supports meaningful understanding, and accounts for the circumstances of different studies and populations.¹

The NHC unites nearly 200 national organizations—including leading patient groups, research institutions, providers, caregivers, and businesses across the health care sector—to drive patient-centered health policy. Representing 200+ million Americans with chronic diseases and disabilities, the NHC strengthens its members' collective influence to expand access to quality, affordable, and equitable health care. The NHC fosters collaboration to shape policies that reflect the needs of patients.

NIH's proposal recognizes an important distinction between disseminating scientific information to the research community and communicating study findings to people who participated in the research. Existing requirements for public access, data sharing, and reporting trial results have not created a consistent expectation of direct communication with participants. Studies indicate that participants are interested in receiving aggregate findings. These studies have also identified practical barriers to routinely sharing those findings. An effective NIH policy would close this by ensuring that participants can

¹ National Institutes of Health (NIH), "Request for Information: Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants," NOT-OD-26-113, August 27, 2026, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-113.html>.

readily access and understand study findings, rather than simply requiring a technical summary.^{2,3}

Summary of Recommendations

The NHC recommends that NIH:

- Establish an expectation that participants will be offered aggregate study findings, while preserving the ability of participants to make informed choices about whether and how to receive them;
- Engage participants and patient organizations early in designing, testing, and evaluating communication plans to identify the information participants find most relevant and useful, increase the value of results sharing, and avoid unnecessary administrative burden;
- Specify core content for plain-language summaries, including the study question, population, principal findings, important adverse outcomes where relevant, limitations, uncertainty, and practical implications without presenting the summary as individualized clinical advice;
- Allow flexible, accessible, multilingual, and non-digital communication channels that accommodate disability, health literacy, connectivity, and caregiver needs;
- Clarify reasonable timelines and expectations for interim updates, identify justified exceptions, and explain how the policy applies to early termination, incomplete analyses, longitudinal research, and studies in which direct participant contact is neither feasible nor appropriate;
- Recognize reasonable dissemination and participant-engagement costs as appropriate research activities, with usable templates and shared infrastructure; and
- Assess implementation by measuring whether participants receive and understand the findings, without imposing duplicative or disproportionate reporting requirements.

Return of Study Results Should Be a Meaningful Part of Research Participation

The NHC supports establishing a consistent expectation that participants in NIH-supported clinical research, including clinical trials and non-trial studies, will have an opportunity to receive clear, useful information about study findings. Transparent communication is valuable to participants even when a study does not test a prospective intervention. At the same time, NIH's broad definition of clinical research includes observational, epidemiological, behavioral, outcomes, and health services

² Gina M. Sgro et al., "Return of Aggregate Results to Study Participants: Facilitators, Barriers, and Recommendations," *Contemporary Clinical Trials Communications* 33 (2023): 101136, <https://doi.org/10.1016/j.conctc.2023.101136>.

³ U.S. Department of Health and Human Services, Secretary's Advisory Committee on Human Research Protections (SACHRP), "Recommendations Regarding Return of General Research Results," April 24, 2015, <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-april-24-attachment-d/index.html>.

research. Across these study types, the nature, availability, and timing of interpretable aggregate findings may differ significantly. Some studies may also be conducted without direct participant interaction or access to identifiable contact information, making individual communication infeasible or inappropriate.

NIH should therefore distinguish between the expectation to make meaningful study findings available and the obligation to communicate directly with individual participants. A consistent framework for results sharing should preserve flexibility in the content, timing, and methods of communication. NIH should also provide additional guidance for studies that do not produce readily interpretable aggregate findings or for which direct participant contact is not reasonably feasible.⁴

The NHC's patient-engagement framework emphasizes partnership, reciprocity, transparency, representativeness, outcomes patients care about, and timeliness. These principles inform patient engagement throughout the research process, from study planning to the communication of study findings. For results sharing, early engagement can help researchers understand what information participants want to receive and how they would like to receive it. Gathering this input during study planning is important because participants may lose contact with investigators after completing study procedures or follow-up activities. Researchers can then use that input to anticipate communication needs and develop approaches that are both useful to participants and feasible to implement. The NHC encourages NIH to recognize results sharing as an integral component of patient engagement rather than a separate administrative task performed exclusively at study closeout.^{5,6}

Participants may have different preferences about what information they wish to receive, when they receive it, and how that information is communicated. The NHC encourages NIH to recognize these differences and to avoid assuming that a single approach to returning results will be appropriate for all participants. Communication plans should provide meaningful opportunities for participants to express their preferences, including whether they wish to receive findings, the level of detail they would find useful, and how they would like to receive the information.^{7,8}

⁴ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

⁵ National Health Council (NHC), *The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem* (2019), <https://nationalhealthcouncil.org/additional-resources/patient-engagement-rubric/>.

⁶ Patient-Centered Outcomes Research Institute (PCORI), "Foundational Expectations for Partnerships in Research," updated February 2025, <https://www.pcori.org/engagement-research/engagement-resources/foundational-expectations>.

⁷ Carmen E. Aldinger et al., "Returning Aggregate Results of Clinical Trials: Empirical Data of Patient Preferences," *Journal of Clinical and Translational Science* 2, no. 6 (2018): 356–62, <https://doi.org/10.1017/cts.2018.340>.

⁸ UK Health Research Authority, "Informing Participants," accessed October 14, 2026, <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/informing-participants/>.

Communication Plans Should Reflect Participants' Changing Preferences

The NHC encourages NIH to specify that researchers should explain during recruitment or consent whether aggregate results will be offered, what information participants can expect to receive and when, and how participants can select or update their contact and delivery preferences. Where feasible, researchers could provide choices such as postal mail, email, a secure portal, telephone or video communication, or an in-person explanation. The choice to decline results should be equally respected, and participants should not have to explain that decision or repeatedly opt out. Flexibility in communication methods, timing, and frequency can help ensure that participants receive information in ways that are accessible, practical, and responsive to their individual circumstances.^{9,10}

Participants should be able to update their preferences after enrollment. An individual living with a progressive condition may later prefer caregiver assistance; a participant may move, lose connectivity, prefer a different language, or no longer wish to receive study messages. NIH could encourage a low-burden process for updating preferences during scheduled study contacts, while recognizing that collecting and retaining identifying information indefinitely would create privacy and operational concerns. The process should clearly explain when direct contact is no longer expected and whether a public, accessible summary will remain available.^{11,12}

Where research involves children, adults with impaired decision-making capacity, or participants assisted by caregivers or legally authorized representatives, communication plans should specify who should receive findings and address the participant's preferences and involvement to the extent practicable. Those arrangements should be consistent with applicable consent and privacy requirements, particularly when a participant becomes an adult, changes representatives, or withdraws authorization to contact another person. NIH guidance could use practical scenarios to distinguish communicating an aggregate finding from disclosing participant-specific information.¹³

⁹ Center for Information and Study on Clinical Research Participation (CISCRP), "2023 Perceptions and Insights Study," <https://www.ciscrp.org/2023-perceptions-and-insights-study>.

¹⁰ CISCRP, "2023 Perceptions and Insights Study."

¹¹ SACHRP, "Recommendations Regarding Return of General Research Results."

¹² NHC, Rubric to Capture the Patient Voice.

¹³ National Health Council, "Comments on Key Information and Facilitating Understanding in Informed Consent," April 30, 2024, <https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-key-information-and-facilitating-understanding-in-informed-consent/>.

Plain-Language Summaries Need Consistent Core Content and Participant Testing

A concise summary should tell participants what the study was trying to learn; who participated, while protecting confidentiality; what researchers did; what they found; what they did not find; what remains uncertain; and why the findings may matter. For interventional studies, principal outcomes and relevant safety findings should be presented together where available so that an emphasis on apparent benefits does not distort the overall evidence. For observational or exploratory studies, language should distinguish associations from causal conclusions. A participant should be able to identify the main message without interpreting p-values, specialist terminology, or a clinical trial results table.^{14,15}

NIH guidance should clarify that plain-language summaries should not be incomplete or unduly reassuring. Summaries can state when results were negative, inconclusive, or inconsistent with earlier research, and when the study was underpowered or limited by incomplete follow-up. They should also explain, in plain terms, that aggregate results describe a study population and generally do not establish what occurred for any single participant or whether that participant should change a treatment. These distinctions help prevent misunderstanding while allowing researchers to communicate meaningful uncertainty rather than avoid difficult findings.^{16,17,18}

The NHC supports offering a concise, consistent summary of essential study findings, with optional links or accompanying materials for participants seeking greater detail. A useful approach could include a brief plain-language overview, accessible supplementary materials, and a reliable way for participants to ask follow-up questions. Existing results-sharing practices show that standardized public-facing summaries serve as a starting point for communicating with participants. Researchers can then adapt materials and dissemination methods to the needs of their study populations. The NHC encourages NIH to consider similar approaches when developing implementation guidance, including model language for communicating principal findings, adverse

¹⁴ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

¹⁵ Cindy Brach, ed., Health Literacy Universal Precautions Toolkit, 3rd ed., AHRQ Publication No. 23-0075 (Rockville, MD: Agency for Healthcare Research and Quality, March 2024), <https://www.ahrq.gov/health-literacy/improve/precautions/toolkit.html>.

¹⁶ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

¹⁷ Centers for Disease Control and Prevention, "Clear Communication Index User Guide," <https://www.cdc.gov/ccindex/tool/index.html>

¹⁸ Brach, Health Literacy Universal Precautions Toolkit.

events, limitations, and uncertainty in ways that are understandable without sacrificing scientific accuracy.^{19,20}

Participant input can help researchers assess whether draft communication materials are clear and useful. This input should be gathered early enough to allow revisions where appropriate. The NHC encourages NIH to recognize that the appropriate form and extent of participant involvement will vary according to study size, population, available resources, and research design. Depending on these circumstances, collecting patient input could include review by an established patient advisory group, brief structured interviews, cognitive testing, or feedback from others familiar with the condition being studied, like patient groups. Existing patient advisory structures and established engagement processes may provide that input without requiring new advisory bodies or formal testing of every communication product.

While engagement methods may vary, patients can provide valuable feedback on whether the information is understandable and useful. This input complements investigators' review of draft summaries for scientific accuracy. The NHC's engagement rubric distinguishes substantive partnership and responsiveness from nominal inclusion. NIH guidance could provide examples of proportionate ways to involve patients in developing summaries and respond to their feedback.^{21,22}

Accessibility and Communication Equity Should Be Designed In

An accurate summary is only useful to participants if they can reliably access it. While digital tools may be convenient for some people, researchers should not rely solely on websites or email to share study findings with participants. Participants may need printed information, telephone contact, captioned video, large print materials, accessible electronic documents, screen-reader compatibility, translation, interpretation, or communication with an authorized caregiver. Format and channel should be considered together: PDFs should work with assistive technology, and portals should have accessible sign-in processes.^{23,24}

¹⁹ National Institutes of Health, "Plain Language at NIH," accessed October 14, 2026, <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language-nih>.

²⁰ PCORI, "Returning Study Results to Participants: An Important Responsibility," <https://www.pcori.org/research-related-projects/about-our-research/returning-study-results-participants-important-responsibility>.

²¹ SACHRP, "Recommendations Regarding Return of General Research Results."

²² Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), "Return of Aggregate Results," accessed October 14, 2026, <https://mrctcenter.org/project/aggregate-results/>.

²³ UK Health Research Authority, "Informing Participants."

²⁴ Brach, Health Literacy Universal Precautions Toolkit.

NIH should encourage researchers to identify language and accessibility requirements during initial planning, budget for reasonable communication services and accommodations, and update the plan when a participant's needs change. NIH guidance should support proportionate approaches based on the characteristics and communication needs of enrolled participants. Appropriate formats, translation services, and other accommodations may differ across studies. Researchers should base dissemination plans on their study populations' needs rather than on broad assumptions about race, geography, disability, or educational attainment. The NHC's prior comments on ClinicalTrials.gov modernization emphasized usability and understandability for patients; those priorities also apply to sharing study findings with participants, although direct communication requires additional attention to participants' preferences and access needs.^{25,26}

For community-engaged and population-level research, the NHC encourages NIH to distinguish direct participant communications from broader dissemination of study findings. Patient organizations and community-based partners can help researchers identify relevant audiences, develop accessible communication materials, and share findings with communities that may benefit from the research. These activities can be particularly valuable for people living with rare diseases and other conditions for which patient organizations serve as important sources of information and support. However, broader community dissemination should not automatically replace a study's plan to offer results to enrolled participants when direct contact remains feasible.

For studies conducted without direct participant interaction or access to identifying information, NIH should clarify when publicly accessible summaries, community-level dissemination, or other appropriate communication methods may satisfy the policy's objectives without requiring investigators to collect identifying information solely to facilitate results sharing. Researchers should also avoid releasing information that could indirectly identify participants in very small or geographically concentrated cohorts. Such cases may require tailoring the information disclosed and how findings are aggregated.^{27,28,29}

Timing, Updates, and Study-Specific Circumstances Require Clearer Guidance

The draft proposes that clinical trial results be shared no later than one year after the primary completion date or the applicable ClinicalTrials.gov reporting deadline, whichever is later. For extramural non-trial clinical research, it generally ties

²⁵ National Health Council, "National Library of Medicine's (NLM) Request for Information on ClinicalTrials.gov Modernization," March 12, 2020, <https://nationalhealthcouncil.org/letters-comments/national-library-of-medicines-nlm-request-for-information-on-clinicaltrials-gov-modernization/>.

²⁶ MRCT Center, "Return of Aggregate Results."

²⁷ PCORI, "Return of Aggregate Research Results to Study Participants: Reporting Form," revised June 3, 2020, <https://www.pcori.org/sites/default/files/PCORI-DFRR-Ancillary-Information-Results-Return.pdf>.

²⁸ UK Health Research Authority, "Informing Participants."

²⁹ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

communication to the end of the period of performance if relevant analyses are complete, with an update required if they are not. Intramural research is subject to annual participant status updates. These are reasonable starting points, but they may lead to different timelines for participants when the analytical endpoint, end of funding, manuscript publication, and final long-term follow-up occur at different times.³⁰

The NHC encourages NIH to clarify that sharing should occur once aggregate findings have undergone appropriate scientific review and a reliable participant-facing summary can be prepared. Communication should not automatically depend on journal publication. However, reasonable flexibility may be necessary to address data validation, confidentiality, applicable legal requirements, and the responsible interpretation of incomplete findings. For a longitudinal cohort with multiple waves of analysis, investigators could offer clearly labeled interim findings when scientifically appropriate or explain why a meaningful summary is not yet available. When a study ends early or a primary analysis cannot be completed, participants should ordinarily receive a candid explanation of what happened and what, if anything, can be concluded, unless communication itself is justifiably inappropriate.^{31,32}

NIH's proposed status-update requirements should be strengthened by specifying what a useful update contains: the study's current status; whether results are available; a realistic expected date or triggering milestone for sharing results; where and how participants can obtain them; and a way to ask questions. A notice stating only that analysis is ongoing may meet a formal reporting milestone without providing useful information to participants.

NIH should also clarify whether extramural studies with prolonged post-award analysis or delayed results require further updates to participants after closeout, and how investigators can maintain a communication pathway without retaining unnecessary personal information indefinitely.^{33,34} When communication obligations extend beyond the period of performance, the NHC encourages NIH to establish clear expectations for institutional responsibility, allowable costs, and appropriate funding mechanisms. Requirements for post-award updates should be proportionate to the study and should not create indefinite, unfunded responsibilities for investigators or institutions. NIH could also clarify when a stable, publicly accessible summary or an established institutional contact point of contact may appropriately supplement direct communication after the funded research period concludes.

The NHC supports NIH approval of exceptions when sharing is genuinely inappropriate or infeasible. Offering results should remain the presumption, and the justification for

³⁰ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

³¹ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

³² MRCT Center, "Return of Aggregate Results."

³³ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

³⁴ SACHRP, "Recommendations Regarding Return of General Research Results."

any exception should be proportionate to the circumstances. Guidance should distinguish among studies for which no usable aggregate result can be produced, studies in which direct participant contact is not feasible or appropriate, situations involving substantial reidentification or safety risks, and circumstances in which researchers anticipate administrative difficulties or resource limitations. Administrative inconvenience, ordinary dissemination costs, or findings that are negative or inconclusive should not ordinarily justify withholding results. NIH should nevertheless consider exceptional circumstances in which meaningful dissemination would be infeasible or disproportionate. Any exception should be appropriately justified, with safeguards to prevent routine reliance on exceptions. NIH should also provide a process for addressing unforeseen changes after enrollment and, where appropriate, encourage researchers to explain to participants why the expected communication will not occur.³⁵

Implementation Must Be Supported as a Planned Research Activity

The NHC agrees with NIH's recognition that meaningful results sharing requires adequate resources and advance planning. Developing and implementing effective communication plans may involve preparing summaries, verifying scientific accuracy, obtaining participant feedback, providing translation or interpretation, producing accessible formats, maintaining contact mechanisms, responding to questions, and documenting completion. These activities can create logistical and administrative challenges, particularly for smaller studies and research institutions with limited resources. Existing results-return practices demonstrate the importance of planning and budgeting for dissemination from the outset, rather than treating communication as an unfunded responsibility at study completion.

The NHC therefore encourages NIH to clarify that reasonable and necessary expenses associated with returning study results are allowable under applicable award requirements and may be included in research budgets. NIH should also preserve flexibility in funding and implementation to account for differences in study designs, populations, accessibility needs, and resource requirements.^{36,37,38,39}

NIH can provide resources to support results sharing across studies with different needs. For example, NIH could offer modular templates for interventional trials, observational studies, qualitative research, longitudinal cohorts, and studies ending without interpretable findings; sample consent and preference language; adaptable plain-language explanations of risk and uncertainty; and accessible communication formats. Existing approaches to results return demonstrate how centrally developed

³⁵ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

³⁶ Patient-Centered Outcomes Research Institute, "Returning Study Results to Participants."

³⁷ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

³⁸ MRCT Center, "Return of Aggregate Results."

³⁹ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

plain-language summaries and other shared communication resources can support investigators without requiring each research team develop materials independently. NIH could build on these practices by providing adaptable templates, technical assistance, and opportunities for institutions and research partners to share effective communication strategies. Such resources could reduce duplicative work while allowing investigators to retain responsibility for scientific accuracy and for determining whether particular materials and dissemination methods are appropriate for their study populations.^{40,41,42,43}

Implementation guidance should also clarify the roles of investigators, institutions, institutional review boards (IRBs), participant advisory groups, and NIH institutes and centers. NIH already states that researchers are encouraged to consult research participants, IRBs, and institutional officials. A clear division of responsibilities would help avoid duplicate reviews and clarify who approves changes to participant communications.

Sharing aggregate findings should not create an obligation to provide individualized clinical consultations. However, communication plans should explain how participants can seek help with questions requiring clinical interpretation.^{44,45}

The NHC also encourages NIH to take a proportionate approach to compliance and enforcement, particularly during initial implementation. Technical deficiencies or administrative errors made in good-faith should generally be addressed through clarification, corrective action, and technical assistance before stronger enforcement measures are considered. NIH should distinguish isolated implementation challenges from persistent or deliberate failures to meet participant communication obligations and provide clear guidance on how investigators and institutions can address deficiencies. This approach would preserve accountability while recognizing the operational adjustments that may be necessary across research institutions and study designs.

Accountability Should Measure Meaningful Reach without Imposing Unnecessary Reporting Requirements

The draft proposes that researchers confirm with NIH whether summaries or status updates were provided, generally through existing closeout reporting for extramural work. The NHC supports using established reporting channels but encourages NIH to

⁴⁰ PCORI, "Returning Study Results to Participants."

⁴¹ PCORI, "Foundational Expectations for Partnerships in Research."

⁴² National Institutes of Health, "Clear Communication," accessed October 14, 2026, <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication>.

⁴³ MRCT Center, "Return of Aggregate Results."

⁴⁴ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

⁴⁵ NHC, "Key Information and Facilitating Understanding."

distinguish among preparing a summary, offering it to participants, and successfully delivering it, where measurable. NIH should also assess whether communications materials were accessible and understandable. Existing reporting practices for results sharing demonstrate that investigators can document communication activities, identify barriers to direct participant contact, and describe alternative dissemination approaches without requiring extensive new reporting systems.

Evaluation of understandability should focus on the quality of communication materials and, where feasible, representative participant feedback. Investigators should not be required to verify that every participant received or understood the results. NIH could request a limited number of structured attestations documenting the communication methods used, the status of results-sharing activities, and any circumstances preventing direct communication, without collecting participant-identifying information or imposing duplicative reporting obligations.^{46,47,48}

NIH should assess the policy after implementation in collaboration with patients, caregivers, investigators, research institutions, and organizations experienced in community engagement. A targeted evaluation could examine whether participants report receiving and understanding results, which communication methods are effective, whether some groups face recurring access barriers, and whether researchers identify avoidable administrative costs. Findings could inform updates to templates and guidance as research methods and technologies change.^{49,50}

Conclusion

The NHC appreciates NIH's attention to the longstanding gap between generating research knowledge and sharing findings with the people who make that research possible. The proposed policy offers an opportunity to make respectful communication a dependable part of NIH-supported clinical research while preserving flexibility across studies. Participants should be able to decide whether and how to receive results; summaries should convey meaningful findings and uncertainty in understandable terms; and investigators should have the resources and guidance necessary to honor those commitments across different research settings.^{51,52}

Ultimately, success should not be defined solely by whether a results document exists. It should be judged by whether participants have a genuine opportunity to learn what the research found, understand what those findings do and do not mean, and obtain

⁴⁶ PCORI, "Return of Aggregate Research Results: Reporting Form."

⁴⁷ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

⁴⁸ MRCT Center, "Return of Aggregate Results."

⁴⁹ SACHRP, "Recommendations Regarding Return of General Research Results."

⁵⁰ NIH, "Clear Communication."

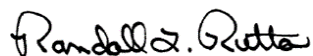
⁵¹ NIH, "Draft NIH Policy on Sharing Summary Level Study Results."

⁵² NHC, Rubric to Capture the Patient Voice.

information in formats that meet their needs. The NHC welcomes continued engagement with NIH as the agency finalizes and implements this policy.^{53,54}

Thank you for the opportunity to provide comments on this RFI. Please do not hesitate to contact Jennifer Dexter, Senior Vice President, Policy and External Affairs, at jdexter@nhcouncil.org, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive, flowing style.

Randall L. Rutta
Chief Executive Officer

⁵³ UK Health Research Authority, "Informing Participants."

⁵⁴ SACHRP, "Recommendations Regarding Return of General Research Results."