MRCT CENTER

THE MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

WEBINAR

Just in Time:
Responding to the NIH Draft Policy on Sharing Summary Study Results

SPEAKERS:

Barbara Bierer
Faculty Director, The MRCT Center

Adam Berger
Director, Division of Clinical and Healthcare Research Policy Office of Science Policy, Office of the Director, NIH

DATE:

Thursday, September 3, 2026

TIME:

1–2 pm ET

REGISTER NOW

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Sharing Summary Level Study Results with Participants: the NIH Draft Policy

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3 September 2026

Disclaimer

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- This work is licensed under a CC BY-NC-SA 4.0 license.
- I have no financial conflicts of interest.
- I am, however, biased. I believe that we should be offering to return results to participants, patients, and people unless there is a justifiable and continuing reason not to.

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MRCT Center is an applied research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

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Goals today

Return of Results to Participants: Regulatory Momentum, NIH, and What's Next

- Examine the growing regulatory and policy focus on providing clinical trial results directly to participants and the general public
- Explore the new draft NIH policy and areas for further NIH guidance
- Discuss potential impact on disclosure programs, resource needs, implementation challenges and open questions

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What is Return of Summary Level Study Results?

In the context of clinical research, "**summary level study results**" refers to an overall, understandable report of what the study found and how individual participation contributed to the creation of generalizable knowledge.

Today, discussing only the return of **Summary Results**

and *not* Individual Results and Data
(e.g., personal data that was collected in the study)

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Why Return of Summary Level Study Results?

- Fulfills participant expectations and supports transparency
- Concordant with the ethical principles of
  - *Justice:* people have a right to their own data and information
  - *Beneficence:* research should maximize the possible benefits to participants
  - *Respect for Persons:* honor and acknowledge participant contributions to science
- Consistent with international standards (e.g., ICH E6(R3), CIOMS, Declaration of Helsinki) and exemplary international regulations (e.g., UK, EU, Others)

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Regulations

- **EU Parliament Regulation (EU) No 536/2014 (2014):**

  The sponsor of a clinical trial must submit "a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines."

  - Timelines are defined as "12 months after the study ends unless delay is scientifically justified."

  Article 37:

  "Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial."

  https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation

- **US federal laws** require listing aggregate results of many studies on ClinicalTrials.gov (but not in plain language)

- **Revised Common Rule addition 45 CFR 46.116(c)(8)**

  "A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions."

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NIH issued draft policy and RFI (August 27, 2026)
(NOT-OD-26-113)

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

Notice Number:
NOT-OD-26-113

Key Dates

Release Date:	August 27, 2026
Response Date:	October 26, 2026

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-113.html/

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Notably, the NIH policy and RFI:

- Applies to all NIH-supported clinical research*
- Applies to all clinical research, including but not limited to clinical trials
- Acknowledges current, inconsistent practices in sharing results with the public
- Establishes the "requirement to responsibly share summary-level study results with clinical research participants in plain language, unless justifiably not appropriate, for all NIH-supported clinical research."
- Clarifies that enforcement actions apply to the recipient institution and may affect future funding decisions

* Excluding 45 CFR 46.104(d)(4) that exempts secondary research for which consent is not required.

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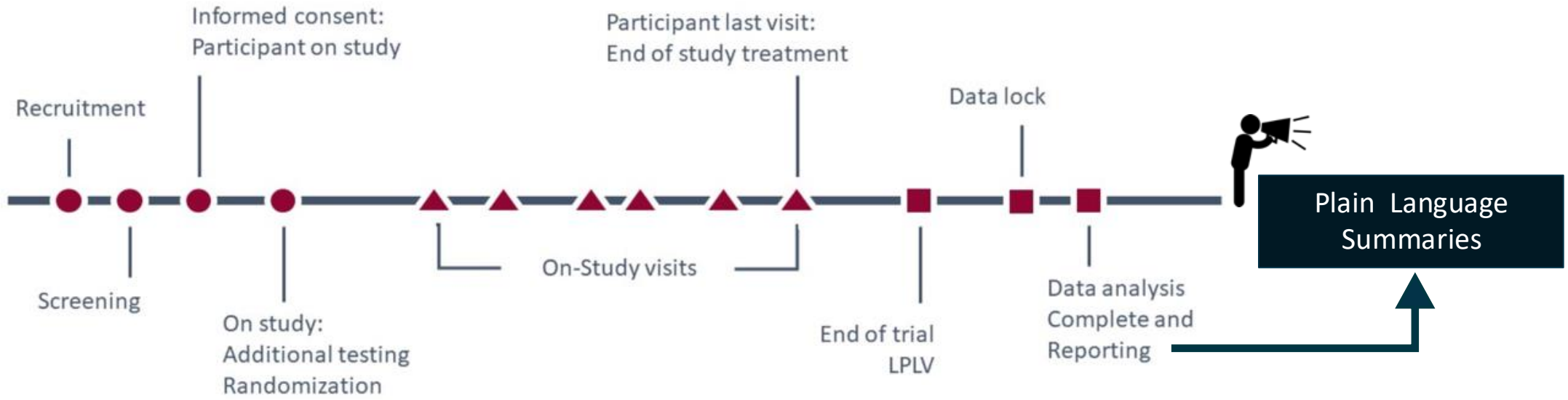
Return of Summary Results: The Participant Clinical Trial Journey

Returning aggregate results begins with commitment and requires planning



- Address whether, what, who, when, and how to return PLS
- (IRB review and approval of plan)

When, how, what

- Introduce plan to participants
- Manage expectations
- Engage and communicate

Who, how

- Prepare PLS aligned with original plan, IC, CSR, manuscript and communications
- Website/individual outreach through PI/sites
- Follow up if needed

When, how, what

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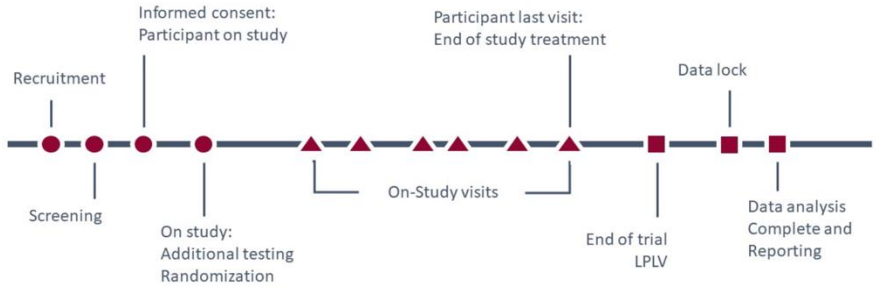
Return of Study Results: Clinical Research

- Clinical Trials
  - RCT, Single Arm
    - Primary v Secondary
  - Platform
  - Pragmatic trials
  - Cluster Randomized Trials
  - Studies that terminate early



- Registry data
- Biospecimen and Data Repositories
- Other Use cases and conditions

- When?
- What?
- How?
- To whom?
- When not?

- Justifiably inadvisable to return? (Study design, condition, population, etc.)

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The NIH policy, and RFI

- Policy is intentionally high-level
- RFI: Supplementary guidelines (e.g., topics, perspectives, preferences with reasoning for opinion)
- Implementation challenges
- Broad application challenges coordination and consistency (e.g., multi-site research, FDA-regulated research, etc.)
- Benefits of flexibility versus clarity

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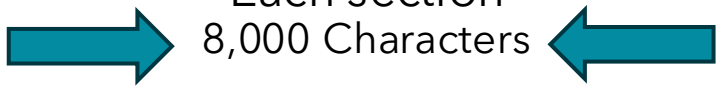
Comments are welcome (October 26, 2026)

"Comments are welcome on all aspects of the draft policy, including the purpose, definitions, scope, effective date, and responsibilities sections. Comments are also sought on specific considerations for how NIH can promote and enable the research community to feasibly share summary level study results with clinical research participants with minimal administrative burden."

Section 1: Draft Policy Components

1. Purpose
2. Definitions
3. Scope
4. Requirements
5. Compliance and enforcement



Section 2: Proposed Supplemental Guidance

1. Participant preferences and experiences
2. Best Practices for Researchers
3. Implementation Needs

Other Comments

https://osp.od.nih.gov/comment-form-draft-sharing-summary-results-policy/

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Turning Discovery Into Health

Building Trust in Science:

Developing a New NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
National Institutes of Health

September 3, 2026

Hot Off the Press! Request for Information (RFI)

Draft Policy on Sharing Summary Level Study Results with Clinical Research Participants

National Institutes of Health
Turning Discovery Into Health

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

Notice Number:
NOT-OD-26-113

Key Dates

Release Date:	August 27, 2026
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Related Announcements

None

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

Background

Partnership with the public is essential to driving meaningful scientific advances capable of improving the health of all. Returning value to individuals who participate in clinical research enhances partnerships and enables NIH to foster innovative health discoveries, strengthen scientific resources to prevent disease, expand medical knowledge, and uphold the highest standards of integrity and accountability in scientific research. As outlined by the Novel and Exceptional Technology and Research Advisory Committee, returning research results is one important strategy for returning value to research participants.

Sharing research results with clinical research participants, their communities, others who could benefit from the results, and the broader scientific audience can improve clinical research engagement, accelerate the pace of scientific progress and improve scientific outcomes to ensure that NIH-supported research translates discoveries into improved health for Americans. Sharing results can, importantly, 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.[1,2,3]

Furthermore, incentivizing participation in clinical research to strengthen retention bolsters rigor in clinical research. Establishing NIH policy to make sharing summary level study results standard practice directly supports the goals of HHS's Operation TrialBlazer, which seeks to strengthen America's leadership in clinical research.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-113.html

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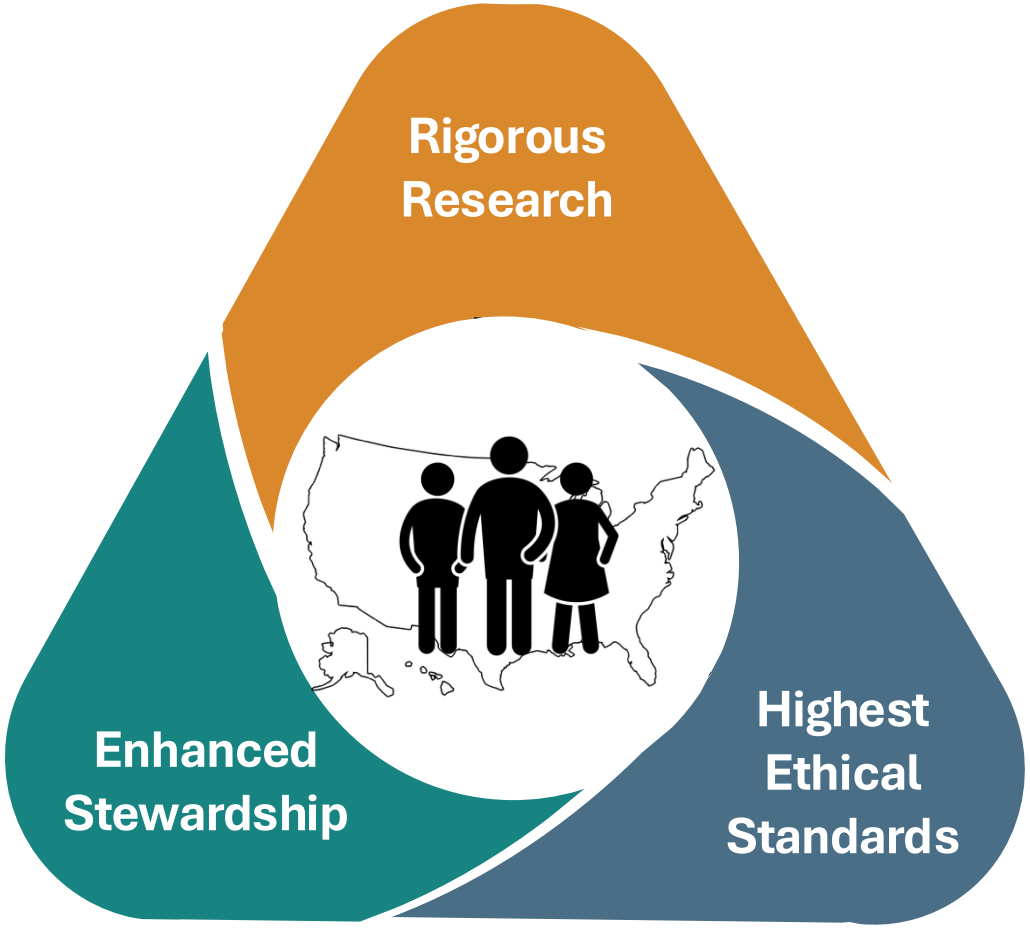
Vision for All Research Involving Human Participants

Goal: Foster Integrity, Transparency, & Trust in Clinical Research

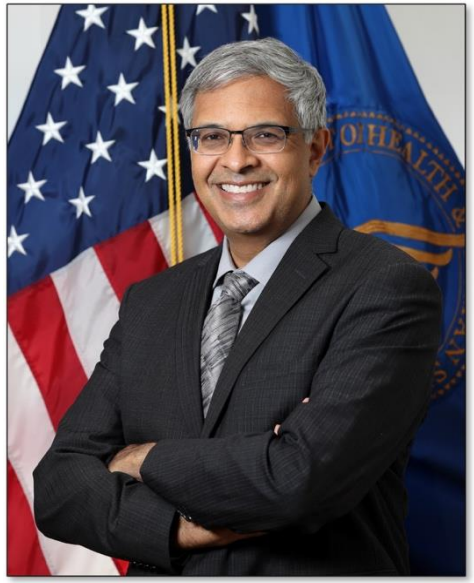


Sharing results with participants is integral to enhancing **engagement** with the public, incentivizing **participation**, and increasing **transparency** and **accountability** to the public for use of taxpayer dollars.

Delivering on Commitments

NIH Director's Statement

Roadmap for Engaging the Public as Partners in Clinical Research



Operation TrialBlazer

HHS Roadmap to Maintain U.S. Leadership in Early Clinical Research and Development

Why share results with participants?

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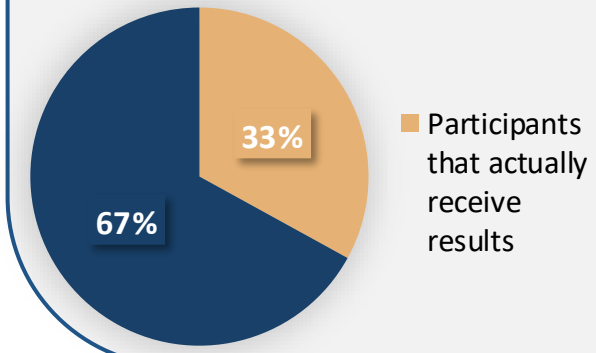
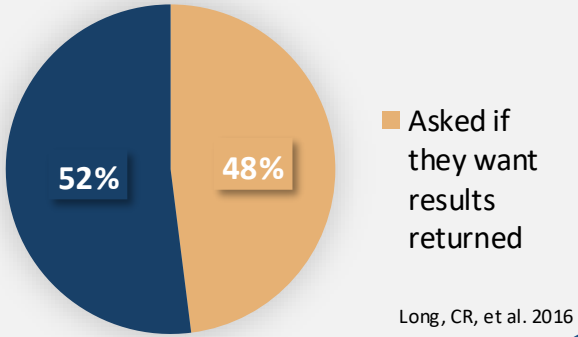
- **98%** of participants want data from studies they participate in
- **72%** more likely to participate in research when results returned
- **70%** more likely to trust researchers in the future

Kent DA, et al. 2024; Wilkins et al., 2019

% of participants who actually receive results



% of participants who are asked if they'd like results



Long, CR, et al. 2016

- Builds trust in science
- Demonstrates respect
- Increases transparency
- Fosters participation in research
- Strengthens rigor
- Enhances use of taxpayer dollars

Draft NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants

Policy Highlights

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Applies to all clinical research supported in whole or in part by NIH, regardless of funding level or mechanism

Requires researchers and institutions to responsibly share summary level study results with participants in plain language for all NIH-supported clinical research

Informed by engagement with the community through an online webinar and on-demand commenting

Draft Policy Requirements

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BOTTOM LINE **NIH-supported researchers conducting clinical research studies are required to share summary level study results in plain language with research participants**

1 WHEN TO SHARE

Clinical trials

No later than 1 year after the primary completion date, or the data results must be reported in ClinicalTrials.gov, whichever is later.

Extramural clinical research (excluding clinical trials)

No later than the end of the period of performance if analyses are complete; otherwise provide NIH and participants a status update to inform when, where, and how they will receive summary level results.

Intramural clinical research

Provide annual status updates to participants beginning no later than 6 months after the policy effective date.

2 PLAN & COMMUNICATE

Design for sharing

Consult with participants, IRBs, and institutional officials to identify effective strategies for integrating the sharing of plain language summaries into study designs and planning phases.

If circumstances change

Changes require NIH approval and IRB approval as necessary; if approved, communicate to participants why results can no longer be shared.

Participant choice

Ensure participants are offered the opportunity to receive summary level study results, regardless of whether they ultimately choose to receive them.

3 EXCEPTIONS & COMPLIANCE

Exceptions

If sharing is justifiably inappropriate, request NIH ICO approval — generally before first participant enrollment.

Default expectation

If no exception is requested or approved, sharing summary level study results is required.

Confirm completion

Confirm to NIH that summary level study results or a status update were provided to participants; extramural institutions should report this in the RPPR during closeout.

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We Want to Hear From You!

Seeking comments on **draft policy proposal** and **proposed supplemental guidance** that may help enable successful implementation while minimizing administrative burden.

Please submit your response to the RFI via the comment form by October 26, 2026!

https://osp.od.nih.gov/comment-form-draft-sharing-summary-results-policy/

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Input Needed:
Draft Policy Components

We're interested in receiving feedback on the following:

- Purpose
- Scope
- Compliance and Enforcement
- General Definitions
- Requirements

Input Needed:
Proposed Supplemental Guidance

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We're interested in receiving information specific to:

Participant preferences and experiences	Information participants, families, and communities find valuable, how they prefer to receive them, what will be communicated, and how to address any concerns about receiving those results.
Best practices for researchers	Developing accessible, culturally appropriate, and low-burden ways to share meaningful results, including key elements and strategies to promote understanding, which results should be returned, when not to share results, and how to communicate with participants or their caregivers.
Implementation needs	Identifying activities, costs, resources, infrastructure, non-monetary supports, and best practices needed to effectively plan for and share understandable, meaningful summary level study results with participants.

Summary Level Study Results Policy Development Timeline

Phase 1: Summer 2026 *(Completed)*	Phase 2: Summer 2026 *(In Progress)*	Phase 3: Fall 2026	Phase 4: Early 2027 & Beyond
• Build awareness of policy development • Engage stakeholder groups to inform draft policy • Hold webinar to get feedback from the public	• Synthesize information gathered through engagement • Release draft policy for public review and comment	• Incorporate feedback received from public comment period into final policy and guidance	• Issue final policy • Partner with stakeholders to address any implementation issues • Conduct outreach and educational activities

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Thank you! Questions? Discussion

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