around a dirty, non-sterile bench area in the basement laboratory where multiple house cats also lingered. Specifically, agents seized from Mr. Thies's residence 90 tablets purporting to be Viagra and 90 tablets purporting to be Cialis. The Viagra and Cialis packaging and pills were counterfeit. The counterfeit marks and trade names, ''Viagra'' and ''Cialis,'' used by Mr. Thies were identical or substantially indistinguishable from the genuine marks owned by Pfizer, Inc./Viatris, Inc. and Eli Lilly & Company, and Mr. Thies used the marks in connection with purported ''sex pills,'' which were likely to confuse or deceive consumers into believing that the product was made by the genuine owner of the trademark. Mr. Thies was present at his residence at the time of the search.

During the search, Mr. Thies admitted to law enforcement that he sold male enhancement pills on his websites, including on *sexpillshop.com*, sometimes receiving up to three orders a day. On January 13, 2023, Mr. Thies met with law enforcement agents and again admitted that he sold male enhancement pills on his websites for years. He also stated he previously sold pills on eBay and social media platforms, but that his accounts were closed upon being told that he could not sell counterfeit products on those platforms.

Law enforcement searched and reviewed the email accounts Mr. Thies operated, including *sexpillshop@gmail.com* and *jeffmetthies@gmail.com.* These email accounts contained lengthy correspondence between Mr. Thies and foreign suppliers of male enhancement pills, ingredients, and packaging, including suppliers from China and India, and customers who purchased pills from his website. At times, Mr. Thies faced impediments to importing counterfeit pills and packaging from foreign countries. When his shipments were seized or took longer to arrive, Mr. Thies would direct his foreign suppliers to use different names and different shipping addresses, in order to disguise or conceal the destination of the shipments. In an email on April 28, 2021, for example, Mr. Thies told a supplier, ''CHANGE IT TO [an alias name] AND MAKE IT APARTMENT #3 INSTEAD OF #1.'' On June 7, 2021, Mr. Thies was made aware through an email from a global shipping company that his package had been detained by United States Customs and Border Protection. Mr. Thies responded by stating, ''I have 2 options[,] contesting isn't one of them.'' In other emails, Mr. Thies was told by foreign suppliers that they were disguising or concealing the contents of shipments to avoid policies that prohibited the sale of certain drugs. For example, Mr. Thies received an email from a Chinese supplier stating, ''[s]ince Alibaba [a Chinese e-commerce marketplace] forbids the sale of sildenafil [the active ingredient in Viagra], we drafted the credit order under the name of NMN, and the real goods are sildenafil.'' Mr. Thies sold over $90,000 worth of pills to consumers throughout the United States during the relevant time period.

FDA sent Mr. Thies, by certified mail, on June 8, 2026, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Thies's felony convictions under Federal law for trafficking in counterfeit goods in violation of 18 U.S.C. 2320(a)(1) and aiding and abetting in violation of 18 U.S.C. 2 were for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Thies illegally smuggled and trafficked counterfeit prescription drug products into the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C that the Agency considered applicable to Mr. Thies's offenses and concluded that the offenses warranted the imposition of a 10-year period of debarment, consisting of two 5-year debarment periods for each felony count to run consecutively.

The proposal informed Mr. Thies of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Thies received the proposal and notice of opportunity for a hearing on June 11, 2026. Mr. Thies failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Jeffrey Thies has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years, consisting of two consecutive 5-year debarment periods as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Thies is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Thies during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19655 Filed 9–24–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: NIH seeks public input on its proposed NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants, including ways to promote and enable the research community to share summary level study results with clinical research participants.

DATES: To ensure consideration, comments must be submitted on or before October 26, 2026.

ADDRESSES: Comments must be submitted electronically to: *https://osp.od.nih.gov/comment-form-draft-sharing-summary-results-policy/.* Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT: Adam Berger, Ph.D., Director, Clinical and Healthcare Research Policy Division, Office of Science Policy, (301) 496–9838 or *SciencePolicy@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

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 (see: *https://osp.od.nih.gov/wp-content/uploads/2025/12/NExTRACs-ENGAGE-Report_FINAL.pdf*), 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 (*see: https://doi.org/10.1136/bmjopen-2025-107270*). (*see: https://doi.org/10.1016/j.conctc.2023.101136*) (*see: https://doi.org/10.1017/cts.2024.568*). 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 (*see: https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf*), which seeks to strengthen America's leadership in clinical research.

NIH has a longstanding commitment to making the results and data generated from the research supported by the agency available to the public and has been taking additional steps to further these efforts to strengthen the science, enhance transparency, create value for communities, and foster trust in research. For example, researchers must proactively plan for how they intend to make their scientific data available under the NIH Policy for Data Management and Sharing (*see: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html*), clinical trials must report their results in *ClinicalTrials.gov* under the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (*see: https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/reporting/nih-policy*), and published results are made accessible to the public under the NIH Public Access Policy (*see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html*). Yet, these efforts have largely focused on sharing data with the scientific community, and not directly to participants.

Some clinical research studies are actively sharing research results with participants. However, the inconsistency in practice across the entirety of the research enterprise leaves a significant gap (see: *https://doi.org/10.1080/17512433.2019.1615441*) (see: *https://pubmed.ncbi.nlm.nih.gov/31827902*). To address this gap and strengthen engagement and transparency with participants, NIH intends to set clear requirements for sharing summary level study results in plain language with participants, unless justifiably not appropriate. Reflecting best practices, the goal of this new policy is to ensure that clinical research participants are responsibly informed about the outcomes and overall results, in ways that are understandable and meaningful to them. Responsible sharing of summary level study results with participants demonstrates that participants are partners in the research process–ensuring findings are shared back with them in an honest, accessible, and thoughtful way that respects the trust and investment to which they contributed.

Summary level study results, also commonly known as aggregate research results, are concise overviews of a clinical research study after all data are compiled and analyzed, with information on the objective, conduct, methodology as appropriate, cumulative outcomes or key findings, relevance, limitations, and potential implications of the clinical research study. Summary level study results are distinct from individual research results that are participant-specific, such as individual lab results. Research participants may want to receive summary level study results for many reasons, including to understand possible implications of the studies they participate in, and where applicable, to inform their health behaviors. Sharing summary level study results with participants has been identified as a best practice by both research participants and the research community, and offering to share summary level study results with participants enhances transparency, demonstrates respect for participants' contributions, and fosters trust and engagement in clinical research.

To inform the development of a Draft Policy on Sharing Summary Level Study Results with Clinical Research Participants, NIH engaged stakeholders in Spring 2026 by seeking input through a public listening session and an on-demand portal for written input. In particular, commenters provided perspectives on topics posed by NIH related to what to include in summary level study results, as well as how and when to share summary level study results with participants. NIH recognizes that many researchers have already employed successful return tactics, and NIH seeks to leverage best practice to implement a minimally low burden approach. NIH also recognizes that expectations for robust sharing of summary level study results with participants may in some cases require additional support for participants for whom summary level study results may provide more questions than answers. Thus, to achieve the goals of a new policy, NIH intends to provide additional supplemental materials for the community, which will also be informed by input received from this request for information.

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

I. Purpose

Through the NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants (also referred to as the Sharing Summary Results Policy), NIH is furthering its commitment to engaging research participants as partners. This Policy would establish the requirement for researchers and institutions to responsibly share summary level study results with clinical research participants in plain language, unless justifiably not appropriate, for all NIH-supported clinical research.

II. Scope

The Sharing Summary Results Policy applies to all clinical research, including clinical trials, supported in whole or in part by NIH, regardless of NIH funding level or funding mechanism, including the NIH Intramural Research Program. This Policy is applicable to all competing award applications, competitive revisions,

proposals for new clinical research contracts or orders, and other funding agreements (*e.g.,* Other Transactions, Cooperative Agreements), received on or after [six months of the publication of a final policy]. This Policy is applicable to all intramural clinical research projects, conducted on or after [six months of the publication of a final policy], including on-going or new studies.

III. Compliance and Enforcement

All recipients of NIH support for clinical research will be required to comply with this Policy, which will be included in the applicable terms and conditions of the award or agreement and in applicable NIH intramural policies and procedures. Failure to comply may provide a basis for enforcement actions, including but not limited to, additional special terms and conditions or termination, consistent with applicable grant regulations; applicable NIH policies and procedures, including NIH intramural policies and procedures; the Federal Acquisition Regulations; and/or other authorities, as appropriate. Enforcement actions may affect future funding decisions for the recipient institution, as authorized in the NIH Grants Policy Statement. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of noncompliance with this Policy, applicable HHS and Public Health Service procedures shall govern.

IV. General Definitions

Clinical Research (*see: https://grants.nih.gov/grants/glossary.htm#ClinicalResearch*).

Research with human subjects that is:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. It includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies; or

2. Epidemiological and behavioral studies; or

3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b)(4) (the ''Common Rule'' prior to July 19, 2018) and 45 CFR part 46.104(d)(4) (the ''Revised Common Rule'' effective July 19, 2018, Exemption 4) are not considered clinical research by this definition.

Clinical Trial (*see: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html*).

Per the NIH Definition of Clinical Trial (*see: https://grants.nih.gov/grants/guide/notice-files/NOT/OD/15/015.html*), a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Plain Language

Communication, including written, verbal, visual, and other methods, that is clear, concise, well-organized, and follows best practices for communicating with public audiences appropriate to the research topic or field, culture, and context. Communication should convey content relevant to the study results without using unnecessary words, jargon, acronyms, or expressions.

Primary Completion Date (see: https://clinicaltrials.gov/study-basics/glossary#p:~:text=a%20clinical%20trial./,Primary%20completion%20date,/The%20date%20on).

The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.

Summary Level Study Results

A concise overview of a clinical research study after all data are compiled and analyzed, with information on the objective, conduct, methodology as appropriate, cumulative/aggregate outcomes or key findings, relevance, limitations, and potential implications of the study.

V. Requirements

The Sharing Summary Results Policy requires NIH-supported researchers conducting clinical research studies to:

- Share summary level study results in plain language with research participants.
  - For clinical trials: no later than one year after the primary completion date, or by the date results must be reported in *ClinicalTrials.gov*in accordance with NIH GPS 4.1.3.1 (see: *https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.3_clinical_trials_registration_and_reporting_in_clinicaltrials.gov_requirement.htm*) or NIH Policy Manual Chapter 3007, whichever is later, to align with existing reporting requirements that are specific to clinical trials.
  - For extramural clinical research that is not a clinical trial: no later than the end of the period of performance, as defined in NIH GPS 1.2 (*see: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm#:~:text=The%20time%20interval%20between,as%20Budget%20period*), if the analyses needed to finalize summary level study results are complete. If the analyses are not completed by this time, researchers must provide a status update to NIH and to research participants to inform them when, where, and how they will receive summary level study results.
  - For all NIH intramural clinical research studies including clinical trials, researchers must provide annual status updates to participants to inform them when, where, and how they will receive summary level study results, beginning no later than six months after the policy effective date.
  - If sharing summary level study results with research participants is justifiably not appropriate and summary level study results will not be shared, exceptions may be requested, subject to NIH Institute, Center, or Office (ICO) approval. Generally, a justification should be submitted before the enrollment of the first participant. If no exception is requested or if the exception is not approved by the NIH ICO, sharing summary level study results is required.
  - Researchers are encouraged to consult with research participants, IRBs, and relevant institutional officials to determine effective strategies for integrating sharing summary level study results with research participants in plain language into clinical research study designs and planning phases to ensure timely sharing with research participants.
- Ensure that research participants are offered, whether or not they receive summary level study results.
- If the clinical research study experiences unforeseen circumstances, and it is no longer possible to share summary level study results, this information must be shared with participants. This communication must provide details on why sharing is no longer possible. Any change is subject to NIH approval. Changes are also subject to IRB approval, as necessary.
- Confirm with NIH that summary level study results were shared, or a status update was provided to research participants. For NIH-funded extramural research institutions, this should occur in the Research Performance Progress Report (RPPR) during close out.

Proposed Supplemental Guidance

The NIH recognizes that meaningful engagement with research participants is already taking place, including studies that are successfully sharing summary level study results with participants and communities. However, as a taxpayer funded institution reliant on public trust and participation, it is critical that the research community work in tandem to share best practices and leverage expertise. Additional resources may be required to ensure participant preferences are prioritized when sharing summary level study results. To that end, NIH is considering the value of issuing supplemental guidance to assist in supporting aspects of this policy, addressing participant preferences and experiences, best practices for researchers, and implementation needs. NIH is seeking feedback on these topics and the corresponding issues listed below. Please note these are proposed rather than final guidance topics and this list is not exhaustive. If you feel additional supplemental guidance is needed beyond what is being proposed, be sure to identify the proposed topic in your response. Your input will help inform and shape potential supplemental guidance aimed at assisting researchers to effectively share summary level study results with clinical research participants.

I. Participant Preferences and Experiences

NIH is seeking input to better understand what information clinical research participants would like to receive as shared summary level study results. The agency believes incorporation of participant preferences is essential for sharing summary level study results in a meaningful way. Participant preferences may be shaped by their personal experiences or by what they believe would be important to know in the future. Your feedback will help ensure researchers develop and share summary level study results that are relevant, valuable, and meaningful to participants; and are transparent in communicating expectations with participants.

The NIH is interested in receiving information on:

- What participants find valuable when receiving summary level study results and what, in addition to the final result(s), they find relevant to be shared.
- Participants' preferred method(s) for receiving summary level study results and expectations for what information should be communicated.
- Participant/family/community concerns about receiving summary level study results, and how they could be addressed.

II. Best Practices for Researchers

NIH recognizes that many researchers are already leading the way in sharing summary level study results with clinical research participants. The agency aims to learn from these existing efforts to identify best practices for the research community. Clinical research encompasses a broad spectrum of research studies, with unique considerations for different scenarios. By understanding how the research community currently prepares and shares summary level findings, NIH can develop potential guidance reflecting this expertise. Your feedback on current methods and challenges will help establish best practices and ensure the research community has the necessary resources to share clear and impactful summary level study results with clinical research participants.

The NIH is interested in receiving information on:

- Effective, low burden approaches for developing summary level study results that are in plain language and culturally and contextually appropriate.
- Key elements that are most important to include, helpful formats, and strategies to promote understanding.
- Considerations for identifying which results should be returned (*e.g.,* primary vs. secondary results) including for specific study populations, study designs, and longitudinal studies.
- Situations where sharing summary level study results is not possible or desirable.
- Considerations for sharing summary level study results with individuals other than the research participants, such as parents/guardians/caregivers of participants.

III. Implementation Needs

NIH acknowledges that sharing summary level study results with clinical research participants requires dedicated resources. The agency is seeking your expertise to identify tools, methods, and resources that are most effective for this process, from creation to dissemination of the summary level study results. Importantly, NIH recognizes that sharing summary level study results with participants, while integral to the research process, will incur costs, and seeks to fully understand the reasonable and necessary costs associated with activities needed to enable sharing of summary level study results. Your feedback will ensure that NIH can provide support and address the implementation needs of the research community.

The NIH is interested in receiving information on:

- Types of activities required to share summary level study results to participants and the anticipated costs associated with those activities for different kinds of studies.
- Information on resources, infrastructure and other non-monetary supports that would help prospectively plan for and implement the requirement to share summary level study results in a way that is understandable and meaningful to all clinical research participants in a study.
- Any existing methods, tools, best practices, or guiding principles that enable sharing summary level study results more effectively.

Request for Input

The National Institutes of Health (NIH) is seeking public input on a new policy proposal requiring summary level study results from NIH supported clinical research to be shared with participants of those studies. NIH is also seeking input on areas for which supplemental guidance would enable successful implementation with minimal administrative burden. Through this policy, NIH intends to strengthen respectful, transparent partnerships with clinical research participants and enable them to benefit through translation of discoveries into improved health.

NIH seeks public input on its proposed NIH Policy on Sharing Summary Level Study Results with Clinical Research Participants, including ways to promote and enable the research community to share summary level study results with clinical research participants. NIH welcomes input from researchers, clinical research participants, clinicians, professional organizations, and other interested members of the public. 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. This feedback may inform the identification of topics and content for potential supplemental guidance.

This notice is being published in accordance with a statement made by the NIH Director found here (*https://www.nih.gov/about/nih/nih/director/statements/roadmap/engaging/public/partners/clinical/research*).

Dated: September 18, 2026.

Matthew Memoli,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2026–19706 Filed 9–24–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent to Request an Revision From OMB of One Current Public Collection of Information: Law Enforcement Officers (LEOs) Flying Armed

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently-approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0072, that we will submit to OMB for a revision in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves gathering information from federal, state, county or municipal armed law enforcement officers (LEOs) who require specialized screening at the checkpoint.