Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18691 Filed 9–11–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Health Information Technology Advisory Committee; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Health Information Technology Advisory Committee (HITAC), originally scheduled for September 24, 2026, from 10:00 a.m. to 3:00 p.m. ET, which was published in the **Federal Register** on January 21, 2026 (91 FR 2542).

The meeting will be held on October 8, 2026, from 10:00 a.m. to 3:00 p.m. ET. The meeting is open to the public and will be held virtually. For web conference instructions and the most up-to-date meeting information, please visit the HITAC calendar at *www.healthit.gov/topic/federal-advisory-committees/hitac-calendar.*

Dated: September 9, 2026.

Tara Porter,

Designated Federal Officer, HITAC.

[FR Doc. 2026–18682 Filed 9–11–26; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NIH Electronic Application System for NIH Certificates of Confidentiality (CoC)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Science Policy (OSP), in the Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, Email your comment or request, including your address to: *NIH-CoC-Coordinator@mail.nih.gov* or contact: Dr. Adam Berger, Division of Clinical and Healthcare Research Policy, Office of Science Policy, OD, NIH, 6705 Rockledge Drive, Suite 630, Bethesda, MD 20892, or call non-toll-free number (301) 496–9838. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, REVISION, exp., date 08/31/2028. Office of Science Policy (OSP), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this electronic system is to submit and process requests for NIH to issue discretionary Certificates of Confidentiality (CoC) to research organizations that request a CoC from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by specific agencies of the Department of Health and Human Services (DHHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of research participants to anyone not connected with the research, except in limited circumstances specified in statute. At NIH, the issuance of CoCs has been delegated to the NIH Office of Science Policy (OSP) in the NIH Office of the Director. The NIH has been using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes 27 questions to collect information from research organizations and six Institutional Assurance statements to be affirmed by the Institutional Official. The information provided is used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC are issued a Certificate of Confidentiality. This system has increased efficiency and reduced burden for both requesters and NIH staff who currently process these requests. NIH received 518 requests for CoCs from January 202*5* through December 202*5* and expects to receive approximately the same number of requests in subsequent years.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 777.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Individuals	518	1	90/60	777
Total		518		777

Dated: September 8, 2026.

Matthew J. Memoli,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2026–18647 Filed 9–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NIH Biosafety Policy for Research Involving Biohazards

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: As the world's largest public funder of biomedical research, the National Institutes of Health (NIH) is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions. To achieve this goal, NIH is proposing a new policy that modernizes and strengthens biosafety practices to ensure that oversight keeps pace with evolving risks. NIH is requesting public input on a new, comprehensive biosafety policy proposal that, when finalized, will replace the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*).

DATES: To ensure consideration, comments must be submitted on or before October 19, 2026.

ADDRESSES: Comments must be submitted electronically to: *https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/*.

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: Cari Young, Sc.M., Director of the Biosafety, Biosecurity, and Emerging Biotechnology Policy Division, Office of Science Policy, (301) 496–9838 or *SciencePolicy@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Nearly 50 years ago, NIH introduced the foundational Guidelines for Research Involving Recombinant DNA Molecules (*https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf*), which established the biosafety framework for much of today's research enterprise. However, the increasingly multi-disciplinary, cross-sector, and global nature of modern science calls for a paradigm shift and, on September 9, 2025, NIH announced (*https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight*) it was beginning a process to modernize and strengthen the oversight of biosafety, to ensure that it is transparent, adaptive, and accountable.

To inform the initial policy proposal, NIH undertook an intensive community outreach and engagement effort (*https://osp.od.nih.gov/table-of-biosafety-engagements-modernizing-and-strengthening-biosafety-oversight/*), hearing from researchers, biosafety professionals, members of the public, and more. Comments were solicited through six regional listening sessions, smaller engagements with groups throughout the United States, and an on-demand portal to receive individual comments for the duration of the community engagement effort.

The feedback received to date has informed a new policy proposal that expands the scope of the NIH Guidelines to all biohazards while removing red tape for low-risk research. As part of this modernization, NIH also seeks to strengthen the role of Institutional Biosafety Committees (IBCs) and reinforce consistency with Institutional Review Boards and Institutional Animal Care and Use Committees, which serve as three foundational pillars of institutional oversight of biomedical research.

Through this draft policy, NIH aims to augment public safety, transparency, and accountability in its stewardship of the biomedical research enterprise. NIH recognizes that resources and guidance will be required to achieve successful implementation of a modernized biosafety policy. Thus, NIH intends to provide additional supplemental materials for the community through implementation resources. These materials will include information about IBC functions, as well as content drawn from existing information, such as biosafety considerations for research with gene drive modified organisms (*https://osp.od.nih.gov/wp-content/uploads/2024/03/gdmo-reference.pdf*), Risk Group (RG) classifications (currently articulated in Appendix B of the NIH Guidelines); and additional information about requirements for containment practices, occupational health plans, and training for research with RG3 influenza viruses (currently articulated in Section III–D–7 and Appendix G–II–C–5 of the NIH Guidelines).

Draft NIH Biosafety Policy for Research Involving Biohazards

Scope and Applicability

Section I. Purpose

As the world's largest public funder of biomedical research, NIH is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions. The purpose of the NIH Biosafety Policy for Research Involving Biohazards (the Policy) is to achieve this goal by setting forth requirements for federal and local institutional oversight of biomedical research involving biohazards, and to help ensure the safe, responsible, and secure conduct of such research.

Section II. Scope

The NIH Biosafety Policy covers all biomedical research, in laboratory settings, involving biohazards.

For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:

1. Wild-type biological agents (*i.e.,* bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above.

This Policy applies to research 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 contracts, and other funding agreements (*e.g.,* Other Transactions, Cooperative Agreements) on or after [effective date will be 6 months from publication of the final Policy], and all existing awards and agreements as of that date. This Policy is applicable to all intramural research projects conducted on or after [effective date will be 6 months from publication of final Policy], including on-going or new studies. This Policy is also applicable to non-NIH funded research that is conducted on or after [effective