DEPARTMENT OF HEALTH & HUMAN SERVICES





Centers for Disease Control and Prevention

CDC has Updated the Operational Policy "Clearance of Scientific Information Products Disseminated Outside of CDC for Public Use"

1. Summary of Policy:

CDC is committed to ensuring that its scientific information products are scientifically sound, technically accurate, and made available in a timely manner. This policy provides direction on roles and responsibilities, timelines, and procedural considerations related to the development, clearance, and cross-clearance of scientific information products.

2. Reason for Revision:

The revised policy updates organizational roles and responsibilities and provides new guidance on the use of the e-Clearance system.

3. Related Issuances:

None

4. Responsible Organization:

Office of Science (OS)

5. Material Superseded:

None

6. Recertification:

This policy is due for recertification on or before the last working day in May 2025.

7. Points of Contact:

Kiana Morris, OS (404-718-4604; <u>inf5@cdc.gov</u>), or Thomas Jones, SBI (770-488-4777; <u>tcj5@cdc.gov</u>)

8. To go directly to the Policy, enter the following URL into the location line of your browser: https://cdc.sharepoint.com/sites/SBI/CDCOperationalDocuments/CDC-GA-2005-06.pdf

> /s/ Sherri A. Berger, MSPH Chief Operating Officer

**References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

Category: General Administration Policy #: CDC-GA-2005-06 Date of Issue: 7/22/2005, Updated 05/18/2020¹ Proponent: Office of Science (OS) Application: All CDC Domestic and International Locations Applicable: CDC Employees and Non-Employees

CLEARANCE OF SCIENTIFIC INFORMATION PRODUCTS DISSEMINATED OUTSIDE OF CDC FOR PUBLIC USE

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1. PURPOSE AND SCOPE

The Centers for Disease Control and Prevention (CDC)² is committed to ensuring that its scientific information products are scientifically sound, technically accurate, and made available in a timely manner. This commitment includes scientific products that are authored or published by CDC employees³ and, as appropriate, non-employees.⁴ This policy instructs CDC employees and non-employees involved in these activities on applicable roles and responsibilities, timelines, and procedural considerations related to the development, clearance, and cross-clearance of scientific information products. Additional considerations for managing the multi-sector workforce are outlined in <u>Section 3.D.</u>

This policy applies to all CDC employees and non-employees at all locations, domestic and international, and to all Centers, Institute, and Offices (CIOs) and Business Services Offices, which are hereafter called "CDC Components"⁵ unless otherwise noted.

Some types of information products will not have scientific content but may require communication and policy review and clearance. This policy does not address communication, media, or policy review and clearance requirements related to those products. The CDC Office of Communications (OC) and the <u>Office of Policy</u>, <u>Performance</u>, and <u>Evaluation (OPPE)</u>

¹ Policy updated to specify the use of the eClearance system and cross- CDC Component clearance requirements, as well as to clarify the categories of individuals to whom the policy applies.

² References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

³ For the purposes of this policy, the term "employees" consists of members of the civil service, Commissioned Corps officers, and locally employed staff. For more information on these categories, refer to "Employee Categories (Updated July 2018)," available at: <u>http://intranet.cdc.gov/ocio/docs/systems-tools/EmployeeCategoryHelp_July_2018.pdf</u>.

⁴ For the purposes of this policy, the term "non-employees" includes individuals who provide consistent services to CDC, maintain a regular presence on a CDC facility, or have been issued a physical or logical access credential and are funded by CDC-managed appropriations. As used in this policy, non-employees include groups of individuals such as guest researchers, contractors, Intergovernmental Personnel Act (IPA) personnel, or students. For more information on these categories, refer to "Non-Employee Categories (Updated July 2018)," available at: http://intranet.cdc.gov/ocio/docs/systems-tools/Non-EmployeeCategoryHelp_July_2018.pdf.

⁵ More information on CDC organizational nomenclature is available at: <u>https://sbi.cdc.gov/DOA/pdf/orgnom.pdf</u>.

should be contacted for information relating to clearance for information products with communication and policy content, respectively.

2. BACKGROUND

In this policy, clearance is defined as the process of conducting reviews and obtaining approvals before scientific information products are released to the public. This policy has been developed to promote consistent scientific clearance procedures throughout CDC to ensure that reviews are performed as efficiently as possible. The policy also describes clearance requirements to be used within and across CDC Components. CDC Components should ensure their processes for scientific clearance align with these requirements.

This policy complements and should be read in conjunction with the Department of Health and Human Services (HHS) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, which includes Part II. D—Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry. The policy also complements the <u>CDC Authorship Policy</u>, which describes the criteria for CDC employees and non-employees to be listed as authors of information products.

3. POLICY

A. Clearance

Component Procedures

Each CDC Component must develop, document, and implement clearance procedures for its respective organization that are consistent with the steps outlined in this policy. These clearance procedures include:

- Issuing information product development (pre-clearance) procedures
- Identifying appropriate reviewers, approvers, and coordinators to facilitate clearance
- Developing procedures to handle information products related to public health emergencies
- Establishing timelines
- Establishing procedures to consider or resolve opposing, or differing viewpoints provided in comments regarding a scientific information product

A CDC Component's clearance coordinator may fall under the supervision of the Component's Associate Director for Science (ADS) or another office that can work with the CDC Components' ADS.

Additional information on Component procedural considerations is outlined in Section 3.D.

Component Clearance Matrices

Each CDC Component must also develop and maintain a clearance matrix and publish it on the Component's CDC Intranet site. The process for developing the clearance matrix should involve, at a minimum, the CDC Component's Associate Director for Communication (ADC), Associate Director for Policy (ADP), and ADS. This matrix provides Component-specific

guidance about the organizational level of review required for specified scientific information products.

The clearance matrix should also identify those CDC Components that need to be made aware of a product, but do not have approval authority. The highest organizational level of review for clearing scientific information products should be commensurate with the following aspects of the particular product:

- Visibility or breadth of dissemination
- Topic's level of sensitivity
- Importance of findings
- Scientific or technical complexity
- Potential to affect other CDC recommendations, policies, or programs
- Urgency of need for dissemination

Products Subject to Clearance

Scientific information products subject to clearance include, but are not limited to:

- Manuscripts
- Guidelines
- Editorials
- Letters to the editor
- Books and book chapters
- Abstracts and presentations for scientific conferences and meetings
- Scientific content for applications on smart phones and other electronic devices

Republished Content

CDC Components have the discretion to republish previously approved products on the internet as long as they are posted verbatim or are condensed without modifying content.

eClearance System

CDC uses eClearance, a web-based tool that automates CDC's clearance process for scientific information products. The <u>eClearance</u> system is used by employees and as appropriate, non-employees for clearance of scientific information products. The first or corresponding CDC author serves as the point-of-contact for clearance and is responsible for submitting the document and all supporting materials necessary for reviewers' awareness (e.g., clearance forms, drafts in tracked changes, reviewer comments, and emails) into eClearance and communicating clearance-related actions to coauthors. Authors are required to keep hardcopies of materials that cannot be uploaded electronically into eClearance.

B. Cross-Clearance

Cross-clearance is the process of obtaining approval from one or more CDC Components.⁶ Cross-clearance is not complete until approvals are received from all CDC Components that share responsibility for program areas covered in an information product. This process allows CDC Components to review and comment on subject matter content that is relevant to their program. Cross-clearance is not necessary when an author's organization does not have programmatic responsibility for the topic or content in the information product.

All substantive comments raised during the originating CDC Component-specific clearance process should be addressed before cross-clearance begins.

C. Information Product Development and Review ("Pre-Clearance")

Pre-Clearance refers to the preparation and review of the information product prior to submitting the product into the eClearance system and initiating the formal clearance process. Before submitting products for clearance, authors and their supervisors should ensure products meet high quality standards by doing the following:

- Base information on sound, ethical science
- Ensure materials are well written and professionally presented
- Conduct appropriate peer-to-peer reviews
- Ensure a Writer-Editor reviews the product, if needed
- Determine if the information product is consistent with CDC recommendations and policies
- Alert appropriate employees, and as appropriate, non-employees, in other CDC Components if findings may impact CDC recommendations or policies
- Consult with experts within the originating organization or other stakeholders, such as the Office of the General Counsel (OGC) or OPPE, for information products that include or may implicate their subject matter areas
- Obtain independent statistical or additional subject-matter review to provide added value if complex methods are used or when statistical review is anticipated for an outside submission

D. Procedural Considerations

The following elements must be included when CDC Components develop and document internal clearance procedures.

Clearance Timelines

CDC Components are responsible for setting timelines for the review and approval of scientific information products. Timelines are established based on the length and complexity of each product and the responsibilities of each clearance official. CDC Components are encouraged to minimize the time taken for clearance especially for the shortest, simplest information products and for products being prepared in response to time-sensitive issues, such as a public health emergency or a news event. Clearance approval should take 30 calendar days or less (including all reviews and revisions), although the process may take longer, depending upon

⁶ Because the National Center for Health Statistics (NCHS) is a federal statistical agency, its official statistical reports are not cross-cleared even if the content is relevant to another CDC Component. However, such documents may be shared with technical staff in other CDC Components as needed. Please consult the NCHS Associate Director for Science for additional guidance.

circumstantial factors, such as when an information product is more lengthy, complex, or requires revisions.

CDC Components are responsible for setting up other procedures to ensure routine clearance occurs as efficiently as possible. Such procedures include designating alternate points of contact to provide clearance when an official is unavailable and evaluating and improving clearance processes.

Cross-Clearance Timelines

Information products should be approved by the originating CDC Component during the Component's clearance process and before submission for cross-clearance. Cross-clearing CDC Components have 10 business days to complete cross-clearance requests from other CDC Components. The originating CDC Component's ADS has authority to extend deadlines if there is a reasonable request from the cross-clearing organization.

When a CDC author uses a public-use data set from the National Center for Health Statistics (NCHS), but there is no coauthor from NCHS, then the ADS in the originating CDC Component should forward an information copy to the NCHS ADS. Comments, if any, will be returned within 10 working days.

If the cross-clearing organization does not complete the clearance process within the 10business-day review period or obtain approval for an extension, then the originating organization is permitted to move forward with the understanding that no comments were submitted. After 10 business days, the originating CDC Component can enter "no comments submitted" in the comment section of eClearance and withdraw the product from the e-Clearance system.

Records Management and Retention

eClearance serves as the CDC record for the final information products disseminated outside the CDC for public use and all the clearance versions associated with eClearance. Outside of eClearance, there may be paper-based or electronic versions of published and unpublished information products developed by employees and non-employees from completed projects, along with substantive supporting materials that contribute to the understanding of the final report. These versions should be permanently retained in accordance with the <u>CDC Records Management Policy</u>.

Draft and final information products produced by CDC employees and non-employees that are funded by CDC and created in the course of federal business are federal records. As such, drafts and published products belong to the federal government and cannot be removed from the government's possession.

Multi-Sector Workforce Considerations

To support its mission, CDC may leverage the expertise or skills of non-employees to develop scientific informational products. Non-employees include, but are not limited to, contractors. CDC Components must remain cognizant of their responsibilities to manage appropriately the multi-sector workforce (see CDC-HR-2012-01, "<u>Managing the Multi-Sector Workforce</u>"). CDC Components should contact the Office of Financial Resources (OFR), Human Resources Office (HRO), or the Office of the General Counsel (OGC) for additional guidance on managing the

Multi-Sector Workforce to ensure appropriate engagement of non-employees in the development of scientific information products and application of this policy to such non-employees.

4. RESPONSIBILITIES

A. Office of Science (OS)

- Provides CDC-level review and approval of scientific information products
- Mediates clearance issues that cannot be resolved at the CDC Component level
- Maintains the eClearance system infrastructure
- Provides guidance to CDC Components as needed
- Updates this policy as required

B. CDC Components

- Determine the clearance requirement for each information product and record the requirements and timelines in a clearance matrix
- Maintain a current clearance matrix on the CDC Intranet identifying the component clearance process
- Develop Component-specific scientific clearance and implementation procedures that are consistent with this policy
- Develop processes to expedite clearance and cross-clearance for information products requiring immediate release during public health emergencies
- Assign at least one clearance coordinator to send, receive, and distribute requests for cross-clearance from other CDC Components
- Publish a current contact list of all clearance coordinators on the CDC Intranet and update the list regularly
- Provide documentation, training, and mentoring to ensure employees and nonemployees understand the intent of clearance requirements, the CDC Component's clearance procedures, and the importance of submitting information products only when they are ready for clearance
- Develop a process for resolving disputes arising during clearance and refer disputes that cannot be resolved by the CDC Components to OS for resolution
- Monitor and evaluate clearance processes to ensure the Component establishes timelines and implements process improvements
- Coordinate with appropriate CDC staff in the Associate Director for Policy's Office of Acquisition Services (OFR/OAS) to ensure that products developed under contract for CDC comply with this policy
- Assign a designated point of contact to manage the responsibilities of the CDC Component's ADS if the CDC Component does not have one

C. CDC Component Associate Directors for Science (ADS)

• Manage the clearance process, coordinating with Associate Directors for Communication (ADC) or Policy (ADP) as required by the CDC Component

- Assist in the development and approval of CDC Component's internal clearance procedures, consistent with this policy
- Approve clearance of CDC Component's internal scientific information products
- Determine which CDC Components will be requested to provide cross-clearance
- Share the information product with other CDC Components as appropriate, for informational purposes, when cross-clearance is not required
- Review cross-clearance comments before returning the information product to the originating CDC Component
- Review cross-clearance comments received from the cross-clearing CDC Component before returning the information product to the author

D. Clearance Coordinators

- Advise authors on requirements for CDC Component cross-clearance
- Request cross-clearance from other CDC Components
- Assist the Component ADS on clearance issues
- Manage the receipt, internal distribution, and return of information products received for cross-clearance from other CDC Components

E. Employees and Non-Employees with Clearance and Cross-Clearance Responsibilities

- Maintain sufficient up-to-date scientific, technical, organizational knowledge, and depthof-experience in a program area to qualify themselves to certify that information relevant to that program area is of high quality
- Assign another individual to perform clearance or cross-clearance responsibilities, or notify Division or CDC Component's management of the need for a temporary replacement, when on leave or otherwise unavailable
- Recuse themselves from clearance responsibilities when there is a conflict of interest, to include but not be limited to if they are authors, and request the originating CDC Component's ADS to appoint an alternative clearance official at an equal or higher organizational level
- Ensure that the information product reviewed is of high quality, scientifically sound, and useful to the intended audience
- Identify clearly each comment as "Required" (i.e., a revision or a response from the author is required to be made) or "Suggested" (i.e., comments are for consideration)
- Evaluate the list of approvals to ensure the clearance is adequate and request additional approvals from within other CDC Components, if needed⁷

F. CDC Authors – First or Corresponding CDC Author

- Obtain written concurrences from all coauthors (CDC and non-CDC) prior to submitting information products for clearance
- Obtain clearance for information products
- Ensure CDC data being used in the information product are described correctly and made available according to the <u>CDC Policy on Public Health Research and</u> <u>Nonresearch Data Management and Access</u>
- Contact the source of the comments to resolve concerns for internal CDC Component clearance as needed

⁷ This responsibility is done by the last clearance official in the originating CDC Component.

• Document and share with coauthors substantive review comments and obtain written concurrence with the final draft

G. CDC Authors – First-Listed CDC Co-Author (When CDC is Not the First or Corresponding Author)

- Obtain written concurrences from all CDC coauthors **NOTE:** Non-CDC coauthors concurrence is not required for eClearance.
- Obtain clearance for information products
- Document and share substantive comments with all authors

5. REFERENCES

- A. CDC. CDC-GA-2005-08: Authorship Policy, dated August 25, 2016, https://cdc.sharepoint.com/sites/SBI/CDCOperationalDocuments/CDC-GA-2005-08.pdf
- B. CDC-HR-2012-01: Managing the Multi-Sector Workforce, dated February 27, 2020, <u>https://cdc.sharepoint.com/sites/SBI/CDCOperationalDoc</u> uments/CDC-HR-2012-01.pdf
- C. CDC. CDC-GA-2005-14: Policy on Public Health Research and Nonresearch Data Management and Access, January 26, 2016, https://cdc.sharepoint.com/sites/SBI/CDCOperationalDoc uments/CDC-GA-2005-14.pdf
- D. CDC. CDC-GA-2005-07: Records Management Policy, dated July 30, 2018, <u>https://cdc.sharepoint.com/sites/SBI/CDCOperationalDoc</u> <u>uments/CDC-GA-2005-07.pdf</u>
- E. CDC. OS Homepage. Last reviewed November 14, 2017, https://intranet.cdc.gov/os/index.html.
- F. HHS. Office of the Assistant Secretary for Planning and Evaluation, "HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public," dated October 1, 2002, <u>https://aspe.hhs.gov/report/hhsguidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-informationdisseminated-public</u>.
- **G.** OMB. Memorandum M-0503: "Final Information Quality Bulletin for Peer Review." Issued December 14, 2004, <u>https://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public.</u>

6. ACRONYMS

- **ADC** Associate Director for Communication
- ADP Associate Director for Policy

ADS - CDC Component-level Associate Director for Science

ATSDR - Agency for Toxic Substances and Disease Registry

CDC - Centers for Disease Control and Prevention

CIO - Centers/Institute/Offices

HHS - Department of Health and Human Services

HRO - Human Resources Office

IPA - Intergovernmental Personnel Act

NCHS - National Center for Health Statistics

OADC - Office of the Associate Director for Communication

OADPS - Office of the Associate Director for Policy and Strategy

OAS - Office of Acquisition Services
OFR - Office of Financial Resources
OGC - Office of the General Counsel
OS - Office of Science
OMB - Office of Management and Budget

7. DEFINITIONS

Author – The individual who makes substantial contributions to the conception, design, or acquisition of data or analysis and interpretation of data; has responsibility for drafting the product or revising it critically for important intellectual content; and approves the final version to be published (see also Coauthor)

CDC Components – Organizational entities of CDC that are comprised of CIOs and Business Services Offices, as outlined in <u>Organizational Nomenclature Used in Delegations of Authority</u>

Clearance – The process of obtaining approvals by the appropriate CDC employees and nonemployees before an information product is released to the public

Clearance Coordinator – The individual responsible for routing information products through clearance

Clearance Matrix – A matrix that displays the information products typically produced by the CDC Component and notes whether clearance is required for that information product, the organizational level of review required, and timelines for clearance officials

Coauthor – Refers to all other CDC and non-CDC authors and includes former CDC personnel when reporting on work conducted while employed with CDC

Corresponding Author – The author responsible for managing correspondence with the journal

Cross-clearance - The process of obtaining approvals from more than one CDC Component

eClearance – The web-based tool that is used at CDC for clearance of scientific information products

First Author - The first person listed on the authorship line

Quality – The utility to the intended audience, objectivity in substance and presentation, and integrity (i.e., protection of information from unauthorized access, revision, or falsification) of a product, as defined in the <u>HHS Guidelines for Ensuring the Quality of Information Disseminated</u> to the Public