



Centers for Disease Control and Prevention
Research and Development Records

Records Management Inspection Report

National Archives and Records Administration
September 19, 2019

**CENTERS FOR DISEASE CONTROL AND PREVENTION
RESEARCH AND DEVELOPMENT RECORDS**

INSPECTION REPORT

INTRODUCTION

The National Archives and Records Administration (NARA) is responsible for assessing the proper management of records in all media within Federal agencies to protect rights, assure government accountability, and preserve and make available records of enduring value. In this capacity, and based on authority granted by 44 United States Code (U.S.C.) 2904(c)(7) and 2906, NARA inspects the records management programs of agencies to ensure compliance with Federal statutes and regulations and to investigate specific issues or concerns. NARA then works with agencies, if necessary, to make improvements to their programs based on inspection findings and recommendations.

In FY 2018, NARA began a series of narrowly focused records management (RM) inspections investigating the management of scientific research and development (R&D) records to identify unique and common challenges, risks, and trends that might be of interest to records management programs in other Federal agencies that create and maintain R&D records. The long-term business need for the data poses unique challenges for preservation, access, and eventual transfer of permanent records to the National Archives. These inspections examine whether science and research centers comply with statutory mandates related to the management of R&D records in an electronic format and on the ability of these centers to transfer permanent R&D records to the National Archives. The overall intent was to determine if science and research centers have essential policies, procedures and processes for the creation, maintenance, and transfer of R&D records to the National Archives.

In March-April 2019, NARA inspected four research projects being conducted by the Centers for Disease Control and Prevention (CDC).¹ The CDC was selected as part of the R&D series of inspections because they create and maintain a large volume of research data. While NARA only inspected a small sample of research studies being conducted by CDC centers, these studies are a good representation of the types of research being undertaken by CDC, approaches that are taken to data stewardship, and the incorporation of RM into agency operations. Further details on the inspection methodology are provided in Appendix A.

¹ In order to carry out its mission, CDC has 16 Centers, Institutes and Offices around the country, <https://www.cdc.gov/about/pdf/organization/cdc-org-chart.pdf>.

OVERVIEW OF CDC RECORDS MANAGEMENT

Records management at CDC is currently part of the Strategic Business Initiative Unit (SBI), which falls under the operational control of the Office of the Chief Operations Officer (OCCO). The operations of the RM program are conducted on a federated basis by the agency Records Officer (RO) who oversees the work of three staff members. The primary function of the CDC RO and her staff is to provide agency-wide oversight for records management by promulgating policies and guidance, creating and updating records schedules, and developing training. The RO works in coordination with Senior Records Liaisons (SRL) appointed by each CDC Center, Institute or Office (CIO). SRLs are responsible for day-to-day RM operations in their respective CIOs. These duties include coordinating the activities of Records Liaisons (RL) in their CIOs, training staff, assisting in the creation of records inventories and file plans, scheduling records, applying dispositions, and conducting evaluations. Each CIO has at least one person serving in an SRL capacity, though this role is often part-time. The SRLs are generally well supported by the RO and her staff who provide programmatic assistance and guidance on an “as-needed” basis.

OVERVIEW OF CDC RESEARCH PROJECT MANAGEMENT

CDC has a standard of practice for data management that research project management staff are expected to follow. The four research projects the NARA inspection team reviewed at CDC are adequately managed throughout the active project lifecycle by principal investigators and project managers. All four projects utilized data management systems to collect, analyze and share data with a wide range of internal and external investigative collaborators. Each project produced collateral documentation and reports that were stored outside of the data management systems in shared electronic files or data hubs. The studies under review utilized some form of classification schemes and naming convention methods to track and maintain their files throughout the project lifecycle. They also used other tools such as file plans, folder maps, and electronic systems inventories. All four studies were longitudinal in nature with three of them being scheduled as permanent by the CDC RM program. Permanent records in both analog and electronic formats have been transferred to NARA according to schedule. Project managers, investigators, and staff were well aware of the need to secure, protect, and maintain their study data and files for the life of the project and organized their files in an efficient manner so that they could be accessed by staff.

KEY OBSERVATIONS

There are four initiatives mentioned in this section that are important to note and that NARA is interested in being kept informed of progress and seeing them completed.

ENTERPRISE SYSTEM CATALOG

It is important to mention that CDC has a robust Enterprise Systems Catalog (ESC) that captures attributes about agency Information Technology (IT) investments. Included in the ESC is an Electronic Systems Inventory (ESI) application that gathers system information from business stewards or project managers about data collection, use, and access. Included in this information are recommendations about system dispositions. All of this information is used to assist the RM program staff in the scheduling of systems. As currently configured the ESI is an excellent tool to track the scheduling of the numerous data management systems utilized and maintained by CDC CIOs. Management of data in the systems listed in the ESI is dependent on CIO SRLs and RLs who should coordinate with research project staff to conduct regular reviews of systems to ensure that the data they contain is in compliance with CDC RM policy.²

RECORDS SCHEDULING

The CDC RO is currently conducting an enterprise-wide records rescheduling effort that includes a review of the existing agency R&D records schedule. The RO is holding focus group meetings to gather input about the schedule, which is now ten years old. The RO used the same process to develop a laboratory series aggregate or “big bucket” schedule which has been completed and is under review. Once submitted to NARA for approval, the new R&D schedule should help to improve implementation of dispositions for research and development records at CDC.

EXIT OR REASSIGNMENT INTERVIEWS

The CDC RO is updating the records management portion of the agency employee departure process to further ensure that records are handled properly by departing or reassigned employees to prevent the alienation or unauthorized disposition of records.

EMAIL HANDLING FOR R&D PROJECTS

The CDC is managing email in accordance with the Department of Health and Human Services (HHS) policies and has applied the Capstone approach to the capture of email of senior agency officials. In addition, other email accounts can be added to Capstone retention rules as permanent records upon request by the staff of a CIO. Implementation of this policy is particularly important in the area of research project management since many projects end up being scheduled as permanent. It was also found that project managers had access to project emails so that if a team member left the project or was reassigned the manager could review the email system and retrieve documents for removal to shared drives for ultimate disposition with other project records. This access was supplemented by that of the CDC RO who could also review

² CDC records management policy is outlined in CDC-GA-2005-07, updated 7/30/2014.

project emails if called upon to do so. This review and centralization is important to proper recordkeeping within the numerous research projects undertaken by CDC.

FINDINGS AND RECOMMENDATIONS

NARA identified areas of the records management program as applied to R&D records that are not compliant with elements of 36 Code of Federal Regulations (CFR) Chapter XII, Subchapter B, that need to be addressed. This report makes three findings and four recommendations. Follow-up actions required for CDC are included in Appendix C.

Finding 1: Implementation of records lifecycle governance at CDC is inconsistent.

CDC RM policy (CDC-GA-2005-07) requires that SRLs work with their CIOs to coordinate “activities such as records retirement and disposition, files set-up and management, and other activities.” CIOs and their assigned SRLs are required to maintain a centralized list and description of official records that includes a standardized arrangement and organization of files. They are also required to create an inventory of records in their respective CIOs and conduct regular reviews to identify new and obsolete records series and systems in order to assist with the scheduling and disposition of records.

There was limited evidence of close interaction between SRLs or RLs with research project staff. In three instances the SRLs or RLs were new to the CIOs and had little knowledge of the projects under review. SRLs and RM program staff sometimes interacted with project staff in the scheduling of data management systems; however, subsequent interactions over the course of the project lifecycle were of a more limited nature, until the final disposition of project records in some instances. Project management staff from the most recent project under review had not discussed the scheduling or disposition of its records with the CIO SRL. Staff in another study had not worked with their SRL to inventory their records. An inventory provided by the SRL had not been updated since 2011. Another study, which has been active since 2001, did not have a files inventory or a standardized file plan. Among research project staff there was some confusion over the need to apply schedule dispositions to temporary and permanent project records maintained outside of data management systems.

CDC practice is to implement the records disposition process once studies have met the end of their active lifecycle or have transitioned to a different stage. Because of the length of the studies close coordination between CIO RM staff and research project staff is required to ensure that both data and records are properly maintained during the lifecycle of a project and in accordance with the requirements in CDC RM Policy.³

³ One study under review has been active for over 50 years.

Recommendation 1.1: SRLs and RLs working with research project staff in their CIOs must ensure that all project records are inventoried, scheduled, and properly dispositioned in accordance with CDC RM Policy and Federal regulations. (CDC-GA-2005-07, 36 CFR 1220.34(i) and 1225.12(a & b))

Recommendation 1.2: SRLs and RLs working with research project staff in their CIOs must review inactive project records and create disposition plans. (36 CFR 1220.32(e))

Finding 2: Research project staff are not creating data management plans (DMP) to ensure that data produced during the projects are properly managed throughout the records lifecycle.

According to CDC operational policy CDC-GA-2005-14, as of January 26, 2016, data management plans (DMP) are required for all new intramural and extramural public health research projects.⁴ Projects begun before that date were required to have a DMP within three years (January 26, 2019) or whenever a data management system underwent a substantial revision, whichever came first. Among the projects required to produce DMPs are those that include data collected exclusively by the CDC, data collected by other agencies or entities that is funded or co-funded by the CDC, and data collected by another entity that becomes part of a CDC data collection or surveillance system.

To assist with the creation of DMPs, the CDC RM program has produced a checklist for the use of project management staff and investigators. This guidance focuses on records management questions such as what data will be produced by a project, how the data files will be used and stored, what protections and agreements are in place for the data, and how the data will be handled over the lifecycle of the project.

Although the deadline for creating DMPs has passed for existing projects, only one project reviewed had created a DMP, and it did not include RM elements suggested by the checklist nor had the assigned SRL reviewed the plan.

The use of DMPs is an essential part of documenting and identifying the permanent records of the research conducted by CDC, which impacts human health around the world. Including records management requirements in the DMPs will help project staff see the correlation between data and records and ensure that records management is included in overall project planning and the data management process.

⁴ <https://www.cdc.gov/maso/policy/policy385.pdf>.

Recommendation 2: The CDC RO, in association with the Office of the Director, should develop policies and procedures to include RM requirements in the creation, review, and monitoring process for DMPs.

Finding 3: The CDC is not conducting RM evaluations of CIOs.

Effective evaluations are an important part of any RM program. In a federated RM structure evaluations are essential to measure the adequacy and effectiveness of agency policies, procedures, and guidance. Evaluations are critical to ensure that CDC CIOs and programs are in compliance with Federal regulations.

36 CFR 1220.34(j) requires agencies to conduct formal evaluations. This requirement is supported by HHS Policy for Records Management, HHS-2015-0004.002, that requires that Departmental Operating Divisions conduct formal evaluations of two of their RM programs annually. CDC records management policy also requires the RO conduct periodic evaluations of internal RM programs while SRLs are tasked with the evaluation of the RM program in their CIOs.

Currently the CDC is not conducting records management evaluations. An effective evaluation program would serve to ensure better coordination between SRLs, RLs and research project staff, and alert the CDC RO to records management issues within the CIOs. The RM program's strategic priorities plan, dated December 4, 2018, includes a goal that the RM program will conduct audits of five CIOs each year. If implemented, evaluations will help to further integrate CDC records management requirements into the activities of research project staff and help ensure CDC's compliance with Federal regulations.

Recommendation 3: The CDC must create by policy or procedure an effective evaluation program that ensures that CIOs are following Departmental and agency operational policy for RM. (36 CFR 1223.34(j), CDC-GA-2005-07, and HHS-2015-0004.002)

CONCLUSION

The standard practices represented by the four CDC research projects reviewed by NARA indicated that R&D records are being managed by project staff throughout the active project lifecycle. However, there are a few areas of concern that CDC needs to address. By making the improvements recommended in this report, CDC will strengthen its compliance with records management requirements; further integrate records management into the existing data management framework; ensure the preservation of its permanent research records; and contribute to CDC's overall mission. The specific recommendations related to issues unique to

these four research projects should serve as touchstones for the CDC RO and SRLs/RLs when evaluating the CIOs and research projects that may have similar challenges.

APPENDIX A

INSPECTION PROCESS

OBJECTIVE AND SCOPE

The objective of this inspection was to determine if R&D records created and maintained by four CDC research projects are in compliance with the Federal Records Act; 36 CFR Chapter XII, Subchapter B; and CDC policy and procedures.

METHODOLOGY

NARA carried out this inspection by conducting site visits at CDC Headquarters in Atlanta, Georgia. NARA also held teleconferences with the National Center for Health Statistics in Hyattsville, Maryland. More specifically, the inspection team:

- Reviewed records management policies, directives, and other documentation provided by CDC;
- Interviewed RM representatives and research project staff at CDC;
- Guided the course of the inspection using a detailed checklist of questions based on Federal statutes, Federal regulations, and NARA guidance; and
- Reviewed CDC responses to current and past annual Records Management Self-Assessments (RMSA) and current and past annual reports of CDC's Senior Agency Official for Records Management (SAORM).

OFFICES VISITED/INTERVIEWED

NARA interviewed staff associated with the research projects at the following CDC Centers in Atlanta, Georgia, March 26-28, 2019:

- National Center for Immunization and Respiratory Diseases
- National Center for Emerging and Zoonotic Infectious Diseases
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

NARA also held a teleconference with research project staff at the National Center for Health Statistics in Hyattsville, MD on April 11, 2019.

APPENDIX B
RELEVANT INSPECTION DOCUMENTATION

HHS Policy for Records Management, HHS-2015-0004.002, November 25, 2015.

In and Out Processing of CDC Employees, Non-Employees, and Affiliates, CDC-GA-2007-01, July 10, 2013.

Records Management, CDC-GA-2005-07, July 30, 2014.

Policy on Public Health Research and Nonresearch Data Management and Access, CDC-GA-2005-14, January 26, 2016.

APPENDIX C

AUTHORITIES AND FOLLOW-UP ACTIONS

AUTHORITIES

- 44 U.S.C. Chapter 29
- 36 CFR Chapter XII, Subchapter B
- 36 CFR 1239, Program Assistance and Inspections

OTHER GUIDANCE

- Office of Management and Budget (OMB)/NARA *Managing Government Records Directive* (M-12-18)
- OMB/NARA *Guidance on Managing Email* (M-14-16)
- Other NARA Bulletins currently in effect

FOLLOW-UP ACTIONS

- ACTION PLAN

CDC will submit to NARA within 60 days after the date of transmittal of this report to the head of the agency a Plan of Corrective Action (PoCA) that specifies how the agency will address each recommendation, including a timeline for completion and proposed progress reporting dates.

- NARA REVIEW

NARA will analyze the adequacy of CDC's action plan, provide comments to CDC on the plan within 60 calendar days of receipt, and assist CDC in implementing recommendations.

- PROGRESS REPORTS

CDC will submit to NARA semi-annual progress reports on the implementation of the action plan until all actions are completed. NARA will inform CDC when progress reports are no longer needed.

APPENDIX D
ACRONYMS AND ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CIO	Center, Institute, or Office
DMP	Data Management Plan
ESC	Enterprise Systems Catalog
ESI	Electronic Systems Inventory
HHS	Department of Health and Human Services
IT	Information Technology
NARA	National Archives and Records Administration
OCOO	Office of the Chief Operations Officer
OMB	Office of Management and Budget
PoCA	Plan of Corrective Action
R&D	Research and Development
RM	Records Management
RMSA	Records Management Self-Assessment
RL	Records Liaison
RO	Records Officer
SAORM	Senior Agency Official for Records Management
SBI	Strategic Business Initiative Unit
SRL	Senior Records Liaison
TB	Tuberculosis
U.S.C.	United States Code



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