

Request for Records Disposition Authority

Records Schedule Number DAA-0511-2021-0001

Schedule Status Approved

Agency or Establishment Substance Abuse and Mental Health Services Administration

Record Group / Scheduling Group Records of the Alcohol, Drug Abuse, and Mental Health Administration

Records Schedule applies to Agency-wide

Schedule Subject Certificates of Confidentiality

Internal agency concurrences will be provided No

Background Information

Certificates of Confidentiality (CC) protects grantees from legal requests for names or other information that would personally identify participants in the evaluation of a grant, project, or contract. Grantees collect data that includes personally identifiable information (PII) using GPRM Modernization Act Tools during the evaluation period of a grant. A CC protects: (1) the grantees from having to comply with subpoenas, court orders, and state reporting laws that request names or other information that would personally identify participants in the evaluation of the grant, project, or contract (2) principal investigators (PIs), lead evaluators (LEs), and their contractors and cooperating agencies who conduct behavioral health research. The CC does not require PIs/LEs to protect the PII, but enables them to do so. PIs/LEs use CCs most often during evaluations when they ask questions of a sensitive nature.

A CC applies to one project or one grant. A separate application is required for each project. The CC is effective from the start date to the estimated end date of the project.

Coverage under the CC begins before a paper copy is received in the mail and on the date an application requesting a CC is complete. Coverage for a CC is retroactive to the start of the study and continues indefinitely. Coverage extends to participants who did not participate but signed up or who are included in data even if the project is no longer active.

CC protections do not extend to participants who join a project after the CC has expired or to projects that have changed significantly since SAMHSA issued the original CC.

CCs are issued under the authority of the Secretary of the Department of Health and Human Services (HHS), by the Public Health and Welfare Act, Research and Investigations Generally, 42 U.S.C. 241(d), and the federal regulation Protection of Identity – Research Subjects, Definitions, 42 CFR Part 2a.2.

SAMHSA only issues CCs to grantees and contractors that receive SAMHSA funding.

SAMHSA CCs cannot be used for: (1) requestors that do not have SAMHSA funding via grant or contract (2) research and evaluations requiring a Food and Drug Administration (FDA) Investigational New Drug (IND) or Investigational Device Exemption (IDE). The FDA must issue Certificates for projects with INDs or IDEs (3) research and evaluation related to law enforcement activities within the purview of 502(c) of the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the federal regulation Protection of Researchers and Research Subjects, Definitions, 21 CFR 1316.21.

Records relating to CCs include:

- Correspondence
- Applications and Issued Certificates of Confidentiality
- Extensions and Amendments
- Applications and Denied Certificates of Confidentiality responses

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
3	0	3	0

GAO Approval

Outline of Records Schedule Items for DAA-0511-2021-0001

Sequence Number	
1	Certificates of Confidentiality
1.1	Certificates of Confidentiality Support Documentation Disposition Authority Number: DAA-0511-2021-0001-0001
1.2	Approved Certificates of Confidentiality Disposition Authority Number: DAA-0511-2021-0001-0002
1.3	Denied Certificates of Confidentiality Disposition Authority Number: DAA-0511-2021-0001-0003

Records Schedule Items

Sequence Number	
1	Certificates of Confidentiality
1.1	Certificates of Confidentiality Support Documentation
	Disposition Authority Number DAA-0511-2021-0001-0001
	Records related to the request for Certificates of Confidentiality include applications, associated documentation, master lists of Certificates of Confidentiality maintained by SAMHSA, and correspondence.
	Final Disposition Temporary
	Item Status Active
	Is this item media neutral? Yes
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No
	Disposition Instruction
	Cutoff Instruction Cutoff annually at expiration of the Certificate of Confidentiality.
	Retention Period Destroy 6 year(s) after cut off.
	Additional Information
	GAO Approval Not Required
1.2	Approved Certificates of Confidentiality
	Disposition Authority Number DAA-0511-2021-0001-0002
	Memos documenting approval of Certificates of Confidentiality.
	Final Disposition Temporary
	Item Status Active
	Is this item media neutral? Yes
	Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No
	Disposition Instruction
	Cutoff Instruction Cutoff annually at expiration of the Certificate of Confidentiality.

1.3

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Denied Certificates of Confidentiality

Disposition Authority Number DAA-0511-2021-0001-0003

Records include applications, associated documentation, and correspondence.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Disposition Instruction

Cutoff Instruction Cutoff annually at notification of denial.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
11/02/2020	Certify	Zintesia Page	Records Management Specialist	Substance Abuse and Mental Health Services Administration - Substance Abuse and Mental Health Services Administration
03/24/2021	Submit for Concurrence	Richard Green	Archivist Specialist	National Archives and Records Administration - ACR3, Appraisal Team 3
03/26/2021	Concur	Margaret Hawkins	Director of Records Management Services	National Records Management Program - ACNR Records Management Services
04/02/2021	Concur	Laurence Brewer	Chief Records Officer	National Records and Archives Administration - National Records and Archives Administration
04/05/2021	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist