Records Schedule Number: DAA-0512-2023-0001 Status: APPROVED
Date Approved: 05/09/2024

#### General Information

Agency or Establishment Health Resources and Services Administration	
Record/Scheduling Group	0512 - Records of the Health Resources and Services Administration
Records Schedule Applies To	Agency Subdivision
Major Subdivision	Office of Planning, Analysis, and Evaluation
Minor Subdivision	Division of Oversight, Reporting and Regulatory Compliance
Schedule Subject	Human Subject Research Protection
Additional Schedule Information	At HRSA, CoCs are issued for research that is funded by HRSA

either partly, entirely and/or through cooperative agreement. As of April of 2022, CoCs have also been issued at HRSA's discretion to agencies or institutions/entities performing sensitive research related to HRSA's mission. CoCs generally expire at the anticipated end of the associated projects, but they protect the project data indefinitely. CoCs can be updated through amendments in cases of major project changes, and can be extended where needed. Prior to March 31, 2022, HRSA issued separate CoC documents, initially in paper (prior to 2020) as well as electronically. From March of 2020 through March of 2022, CoC documents were issued solely electronically. A new HRSA CoC policy went into effect in April 2022, through which eligible research funded by HRSA is considered to be automatically awarded "deemed" CoCs; therefore a CoC document is not longer separately issued for applicable HRSA research. Presently there is no plan for issuance of future CoCs for non-HRSA funded research. Such requests would likely be routed through other applicable federal agencies. This schedule covers those situations where separate documents have been issued. In addition to serving important Human Subjects Research Protection purposes, CoCs may be required by Institutions Research Boards (IRBs) and can also help in recruitment efforts.

#### Records relating to CoCs include:

- Correspondence
- Applications and supporting documentation
- Annual Checklists of CoC requests and status
- Memos of Certificates of Confidentiality issued, including Amendments and Extensions
- Applications and denied Certificates responses

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	SAMHSA Record Schedule Referenced:	
	DAA-0511-2021-0001	
a Classified Version of This	No	

Is There a Classified Version of This Schedule?	No
Is consultation and coordination with	No - the records covered by this schedule do not implicate Tribal
Tribal Governments required?	interests

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### **Item Count**

Total number of disposition items: 3

Number of Temporary disposition items: 3

Number of Permanent disposition items: 0

Number of Items with Disposition Not Approved: 0

Number of Inactive disposition items: 0

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### Outline of Records Schedule Items for DAA-0512-2023-0001

Item #	Title	Disposition
0001	Certificates of Confidentiality-Human Subject	Temporary
	Research Protection: Certificates of Confidentiality	
	Support Documentation	
0002	Certificates of Confidentiality-Human Subject	Temporary
	Research Protection: Approved Certificates of	
	Confidentiality	
0003	Certificates of Confidentiality-Human Subject	Temporary
	Research Protection: Denied Certificates of	
	Confidentiality	

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### **Records Schedule Items**

Group Title	Certificates of Confidentiality-Human Subject Research
1	Protection
Group Description	The records pertain to Certificate Confidentiality Supporting
1	Documentation, Approved Certificates of Confidentiality, and
	Denied Certificates of Confidentiality.
DAA-0512-2023-0001-0001	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Certificates of Confidentiality Support Documentation
Item Description	Records related to the request for Certificates of Confidentiality
	include applications, associated documentation, and master lists
	of Certificates of Confidentiality maintained by HRSA and
	correspondence.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
MANUAL CITATION	
Agency Code	512
SUPERSEDED AGENCY DISPOSIT	ION AUTHORITIES AND GRS DEVIATIONS
Does this item supersede existing	No
disposition authorities?	
Is this item a deviation from the	No
GRS?	
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cutoff annually at expiration of the Certificate of
	Confidentiality.
Retention Period	Destroy 6 year(s) after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by	No
this item national security	
classified?	
GAO Approval Required	No
DAA-0512-2023-0001-0002	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Approved Certificates of Confidentiality
Item Description	Memos documenting approval of Certificates of Confidentiality.
Is this item media neutral?	Yes

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MANUAL CITATION	
Agency Code	512
,	ION AUTHORITIES AND GRS DEVIATIONS
Does this item supersede existing	No
disposition authorities?	
Is this item a deviation from the	No
GRS?	
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cutoff annually at expiration of the Certificate of
	Confidentiality.
Retention Period	Destroy 6 year(s) after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by	No
this item national security	
classified?	
GAO Approval Required	No
DAA-0512-2023-0001-0003	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Denied Certificates of Confidentiality
Item Description	Records include applications, associated documentation, and
	correspondence.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
MANUAL CITATION	
Agency Code	512
SUPERSEDED AGENCY DISPOSIT	ION AUTHORITIES AND GRS DEVIATIONS
Does this item supersede existing	No
disposition authorities?	
Is this item a deviation from the	No
GRS?	
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cutoff annually at notification of denial.
Retention Period	Destroy 3 year(s) after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by	No
this item national security	
classified?	
GAO Approval Required	No

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### **Signatory Information**

Action	User	Date	
Accept	Bethany Reiswig	12/04/2023	
Approve	Colleen Shogan	05/09/2024	

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