

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0611-2023-0003

Status: APPROVED
Date Approved: 01/21/2025

General Information

| | |
|--|---|
| Agency or Establishment | Administration for Strategic Preparedness and Response |
| Record/Scheduling Group | 0611 - Records of the Administration for Strategic Preparedness and Response |
| Records Schedule Applies To | Agency-wide |
| Schedule Subject | Medical Countermeasures |
| Additional Schedule Information | <p>The Biological Advanced Research and Development Authority (BARDA) is an office within the Administration for Strategic Preparedness and Response (ASPR). BARDA uses an integrated, systematic, portfolio-based approach to support advanced research and development of medical countermeasures (MCM) to mitigate Chemical/Biological/Radiological/Nuclear (CRBN) threats, Pandemic Influenza (PI) and Emerging Infectious Diseases (EID). To accomplish this, BARDA has established more than 350 partnerships with industry stakeholders resulting in over 50 FDA approvals, licensures or clearances.</p> <p>ASPR's Medical countermeasure development, research, and acquisition activities are defined by the Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 and Project BioShield Act of 2003; both pieces of legislation were renewed in 2013 under Pandemic and All Hazards Preparedness Reauthorization Act (PAHPRA) and provide a comprehensive listing of mission responsibilities. In 2019, the PAHPA Innovation Act reauthorized BARDA and Project BioShield through 2023.</p> <p>Records created before June 29, 2022 are scheduled under DAA-0468-2013-0003</p> |
| Is There a Classified Version of This Schedule? | No |
| Is consultation and coordination with Tribal Governments required? | No - the records covered by this schedule do not implicate Tribal interests |

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Item Count

Total number of disposition items: 5

Number of Temporary disposition items: 4

Number of Permanent disposition items: 1

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-0611-2023-0003

| Item # | Title | Disposition |
|---------------|--|--------------------|
| 0001 | Medical Countermeasure Advanced Development Activity Records | Permanent |
| 0002 | Project Acquisition Contract Files and All Supporting Contract File Records | Temporary |
| 0003 | Medical Countermeasure Regulatory Records | Temporary |
| 0004 | Manufacturing, Facilities and Engineering Records : Contractor Produced Confidential Specified Deliverables and All Supporting Records | Temporary |
| 0005 | Analytical Decision Support Activity Records : Analytics and Modeling Supporting Records | Temporary |

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Records Schedule Items

| | | |
|---|---|-----------------------|
| DAA-0611-2023-0003-0001 | | STATUS: Active |
| ITEM GENERAL INFORMATION | | |
| Item Title | Medical Countermeasure Advanced Development Activity Records | |
| Item Description | Project activity records include final reports, analysis summaries, formal assessments and recommendations, and analytical policy decisions relating to the research and development of BARDA activities such as pathogen agnostic technologies, reduction in life cycle costs, utility of current vaccines, solving sepsis, and incubating new programs. | |
| Is this item media neutral? | Yes | |
| Is this item a Big Bucket? | No | |
| MANUAL CITATION | | |
| Agency Code | 0611 | |
| Manual Title | Medical Countermeasure Advanced Development Activity Records | |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | | |
| Does this item supersede existing disposition authorities? | No | |
| Is this item a deviation from the GRS? | No | |
| DISPOSITION INSTRUCTION | | |
| Final Disposition | Permanent | |
| Cutoff Instructions | Cut off at end of Calendar year when the records are submitted or finalized. | |
| Are there multiple instructions for this item? | No | |
| Transfer Instruction | Transfer to the National Archives 25 year(s) after cutoff | |
| ADDITIONAL INFORMATION | | |
| Current Records Format | Textual data:30 GB ; Structured data formats:5 MG | |
| Approximate first year of records covered by this authority | 2022 | |
| End year of records covered by this authority | Still being created | |
| Date span of the initial transfer | From: 06/22/2022 To: 12/31/2023 | |
| Frequency of transfer | 1 | |

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| Are any of the records covered by this item subject to a FOIA exemption? | Yes |
| FOIA Exemption(s) | FOIA (b)(4) Trade Secrets and Commercial or Financial Information |

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| DAA-0611-2023-0003-0002 | STATUS: Active |
| ITEM GENERAL INFORMATION | |
| Item Title | Project Acquisition Contract Files and All Supporting Contract File Records |
| Item Description | These records relate to administrative support activities, to include but is not limited to staffing and procedures not directly related to the essential primary purpose of ASPR, declined and cancelled invitations, training materials developed by ASPR, certificates of completion of training courses, and standard operating procedures that do not document the ASPR policies. Final and supporting records containing confidential or proprietary information in the contract files; and all supporting records from non-confidential contract files. Examples of these supporting records are listed in the Federal Acquisition Regulations 4.803, Contents of Contract Files such as: evidence of availability of funds or evidence of required clearances. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0611 |
| Manual Title | Project Acquisition Contract Files and All Supporting Contract File Records |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | Yes |
| GRS Disposition Authority List | |
| Disposition Authority | Title |
| DAA-GRS-2013-0003-0001 | |
| Justification for GRS Deviation | This item is a mix of program and financial records. Agency would like to have one item covering these records. |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |

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| Cutoff Instructions | Cut off at end of Calendar year when the related contract file is closed. |
| Retention Period | Other: Destroy 20 year(s) after cutoff but longer retention may be authorized by BARDA senior leadership. |
| ADDITIONAL INFORMATION | |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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| DAA-0611-2023-0003-0003 | STATUS: Active |
| ITEM GENERAL INFORMATION | |
| Item Title | Medical Countermeasure Regulatory Records |
| Item Description | Medical countermeasure regulatory activities ensure the availability and delivery of safe, effective, and quality medical countermeasures needed in a time of public health emergency and minimize the risks inherent in the regulatory process for Federal investments of BARDA-sponsored medical countermeasures. Regulatory records pertaining to the regulatory review and approval process of medical countermeasures include, but are not limited to, investigational New Drug (IND) applications, Emergency Use Authorizations (EAUs), Reports of Site Audits, Records of Review (ROR), and quality performance measures. These records are finalized when approved by BARDA senior leadership and submitted as appropriate: e.g. FDA submissions are sent to FDA; quality audits are sent to the ASPR Project Officer and shared with the company; or product acceptances are sent to the ASPR Project Officer/Contracting Officer for payment. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0611 |
| Manual Title | Medical Countermeasure Regulatory Records |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |
| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |

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| Cutoff Instructions | Cut off at end of Calendar year when the records are submitted or finalized. |
| Retention Period | Destroy 75 year(s) after cutoff |
| ADDITIONAL INFORMATION | |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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| Group Title | Manufacturing, Facilities and Engineering Records |
| Group Description | Records supporting the building or retrofitting of the U.S. manufacturing infrastructure to enable the rapid production of vaccines, therapeutics, technologies, and other biologics against pandemic influenza and other emerging threats. Records for public- private partnership programs, including but not limited to the Centers for Innovation and Advanced Development and Manufacturing (CIADM) and pandemic influenza vaccine preparedness efforts are also included. These records include contractor produced records such as milestone and deliverable reports and technical review reports that are specified in the contract as the property of the U.S. Government. |
| DAA-0611-2023-0003-0004 | STATUS: Active |
| ITEM GENERAL INFORMATION | |
| Item Title | Contractor Produced Confidential Specified Deliverables and All Supporting Records |
| Item Description | Contractor produced records containing confidential or proprietary information and all supporting the specified deliverables in the contract such as data analysis, research, statistical review, and progress reports. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0611 |
| Manual Title | Contractor Produced Confidential Specified Deliverables and All Supporting Records |
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |

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| DISPOSITION INSTRUCTION | |
| Final Disposition | Temporary |
| Cutoff Instructions | Cut off at end of Calendar year when the related contract file is closed. |
| Retention Period | Destroy 25 year(s) after cutoff |
| ADDITIONAL INFORMATION | |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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| Group Title | Analytical Decision Support Activity Records |
| Group Description | The Analytic Decision Support Activity Records document the development of analyses, processes and decision support systems for medical and public health consequence assessments and public health response capabilities across the chemical, biological, radiological, nuclear, pandemic influenza, and emerging infectious diseases risk-spectrum. These activities support decisions leading to measurable improvements in public health preparedness. The source data for developing these analyses includes, subject matter expert elicitations, open source records and Department of Homeland Security Material Threat Assessment exposure files. |

DAA-0611-2023-0003-0005 **STATUS: Active**

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| ITEM GENERAL INFORMATION | |
| Item Title | Analytics and Modeling Supporting Records |
| Item Description | These records include medical and public health consequence modeling reports, medical public health consequence modeling presentations and the associated dossier for medical and public health consequence modeling studies. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |

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|------------------------|---|
| MANUAL CITATION | |
| Agency Code | 0611 |
| Manual Title | Analytical Decision Activity Supporting Records |

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|---|----|
| SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS | |
| Does this item supersede existing disposition authorities? | No |
| Is this item a deviation from the GRS? | No |

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| Final Disposition | Temporary |
| Cutoff Instructions | Cut off at end of Calendar year when the records are submitted or finalized |
| Retention Period | Other: Destroy 25 year(s) after cutoff but longer retention may be authorized by BARDA senior leadership and the Chief Data Officer. |
| ADDITIONAL INFORMATION | |
| Are any of the records covered by this item national security classified? | No |
| GAO Approval Required | No |

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Signatory Information

| Action | User | Date |
|---------|----------------|------------|
| Approve | Colleen Shogan | 01/21/2025 |