Records Schedule Number: DAA-0611-2023-0004 Status: APPROVED
Date Approved: 05/09/2024

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 | PHEMCE Confidentiality Commitment Form |
| Additional Schedule Information | In 2022, the Administration for Strategic Preparedness and Response (ASPR) was elevated to an Operating Division within the U.S. Department of Health and Human Services (HHS). ASPR realigned functions reflect the changes mandated by the 21st Century Cures Act and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act to address ever-increasing manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and national security. |
| | Biological Advanced Research and Development Authority (BARDA) is an office within ASPR. BARDA uses an integrated, systematic, portfolio-based approach to support advanced research and development of medical countermeasures (MCM) to mitigate |

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective. The PHEMCE is led by the HHS Office of the Assistant Secretary Administration for Strategic Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA).

Chemical/Biological/Radiological/Nuclear (CRBN) threats,

Pandemic Influenza (PI) and Emerging Infectious Diseases (EID).

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| | Core planning activities performed by PHEMCE include, but are not limited to, establishing requirements for civilian medical countermeasures, medical countermeasure preparedness assessment, establishing and prioritizing medical countermeasure requirements, research and development and planning for the acquisition, stockpiling, distribution and utilization of medical countermeasures. These records are scheduled under DAA-0468-2015-0001-0004 Public Health Policy Group, Team, Council, and Committee Records and DAA-0468-2015-0001-0005 Working Records of the Public Health Policy Group, Team, Council, and Committee Records. Note: Public Health Policy records schedule DAA-0468-2015-0001 cover records created before June 29, 2022. Records created after June 29,2022 will fall under a new Public Health Policy records schedule under records group 0611. |
|--|---|
| 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: 1

Number of Temporary disposition items: 1 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-0611-2023-0004

| Item # | Title | Disposition |
|--------|--|-------------|
| 0001 | PHEMCE Confidentiality Commitment Form | Temporary |

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Records Schedule Items

| DAA-0611-2023-0004-0001 | STATUS: Active |
|-----------------------------------|--|
| ITEM GENERAL INFORMATION | SIIICSIIIC |
| Item Title | PHEMCE Confidentiality Commitment Form |
| Item Description | This form is required as stated in the Memorandum of |
| | Understanding with the Food and Drug Administration, Exhibit |
| | B, Appendix I Section II provides the requirements to implement |
| | the form. This form protects the records created from the core |
| | planning activities protecting all ASPR/BARDA staff |
| | interactions and documentation as a part of meetings, discussions, |
| | or other communications regarding the development of the |
| | PHEMCE. These core planning activities include information |
| | that is trade secret, confidential commercial or financial |
| | information, personal privacy information, or pre-decisional or |
| | deliberative information that has been provided to or belongs to |
| | one of the HHS internal agency partners. |
| Is this item media neutral? | Yes |
| Is this item a Big Bucket? | No |
| MANUAL CITATION | |
| Agency Code | 0611 |
| Manual Title | PHEMCE Confidentiality Commitment Form |
| 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 | Cut off at end of Calendar year when the employee formally |
| | departs ASPR. |
| Retention Period | Destroy 6 year(s) after cutoff |
| ADDITIONAL INFORMATION | |
| Legal citation related to record | https://www.fda.gov/about-fda/domestic-mous/mou-225-13-0028 |
| retention (if applicable) | |
| 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 | Valerie Terray | 09/25/2023 |
| Approve | Colleen Shogan | 05/09/2024 |

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