

## Change History Table: Original – Amendments (4)

### **Amendment 4 (May 31, 2024): BARDA BAA-23-100-SOL-00004 List of Changes:**

<b>Amendment 4 (May 31, 2024)</b>
<ol style="list-style-type: none"><li>1. Updates to Area of Interest #7: Diagnostics<ul style="list-style-type: none"><li>• Updated TRL Requirement</li><li>• Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings</li><li>• Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen</li><li>• Updated AOI 7.3. Influenza Diagnostics</li><li>• Updated AOI 7.3.1. Influenza Home-Use Testing (for OTC or Prescription At-home)</li></ul></li><li>2. Updates to Area of Interest #12: Flexible and Strategic Therapeutics (FASTx)<ul style="list-style-type: none"><li>• Updated Guidance for proposals pursuing a PEP or PrEP indication</li><li>• Updated Guidance for proposals pursuing a mAb platform</li><li>• Deleted Important guidance for proposals for SARS-CoV-2</li></ul></li></ol>

### **Amendment 3 (Mar 29, 2024): BARDA BAA-23-100-SOL-00004 List of Changes:**

<b>Amendment 3 (Mar 29, 2024)</b>
<ol style="list-style-type: none"><li>1. Updates to Area of Interest #3: Antimicrobials<ul style="list-style-type: none"><li>• Updated AOI 3.1. MDR Bacteria and Biothreat Pathogens</li><li>• Updated 3.2. MDR Fungal Infections</li></ul></li><li>2. Updates to Area of Interest #5: Chemical Medical Countermeasures<ul style="list-style-type: none"><li>• Updated AOI 5.2. Opioids and Other Respiratory Depressants</li><li>• Updated TRL Requirement</li></ul></li><li>3. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures<ul style="list-style-type: none"><li>• Updated AOI 6.1. Enabling Technologies to Address General Burn &amp; Blast Traumatic Injuries</li><li>• Updated AOI 6.2. Management of Head Injuries in Trauma</li><li>• Updated AOI 6.3. Hemorrhage Control</li><li>• Suspend AOI 6.4. Non-Autologous Topical Products to Prevent or Reduce Burn Wound Conversion</li><li>• Added new AOI 6.5. Management of Blunt Trauma Injuries</li><li>• Added new AOI 6.6. Advanced Imaging Technologies in Management of Trauma</li></ul></li></ol>

**Amendment 3 (Mar 29, 2024)**

- Added new AOI 6.7. Special Instruction for health economic impact assessment of Burn MCMs
  - Added new AOI 6.8 Special Instruction for Platform Agnostic Software for AI Augmentation of Ultrasound Imaging Data.
4. Updates to Area of Interest #7: Diagnostics
- Updated AOI 7.1.3. Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings
  - Updated AOI 7.2.1. Bacterial Antimicrobial Resistance (AMR) Testing Direct from Specimen
  - Suspend AOI 7.2.2. Bacterial vs. Viral Infections: Point-of-Care
  - Updated TRL Requirement

**Amendment 2 (Dec 22, 2023): BARDA BAA-23-100-SOL-00004 List of Changes:**

**Amendment 2 (Dec 22, 2023)**

1. Suspend AOI 9.4 COVID-19 Monoclonal Antibody Therapeutics for Treatment

**Amendment 1 (Nov 9, 2023): BARDA BAA-23-100-SOL-00004 List of Changes:**

**Amendment 1 (Nov 9, 2023)**

1. Updates to Overview Information –
- Updated Research and Development Opportunity Description
  - Updated General Market Research (TechWatch Program),
  - Updated Application Process,
  - Updated Contract and Submission Information,
  - Updated Electronic Portal Submission Instructions
2. Updates to Background
3. Updates to Part I: Development and Technical Objectives
4. Updates to Part IV: Pre-Submission Call and Quad Chart/Market Research Abstract Instructions (Stages 1 & 2)
- Updated Figure 1. BARDA BAA Process Flow Chart
  - Updated Stage 1: Pre-submission Call with Technical POC
5. Updates to Part VI: Proposal Instructions (Stage 3)

**Amendment 1 (Nov 9, 2023)**

- Updates to Stage 3: Proposal Precreation
  - Section M. Past Performance Information &
  - Vol. II, Attachment 10: Past Performance
  - Vol. II, Attachment 11: Reason for the Proposed Award Type
- 6. Updates to Part VII: Proposal Evaluation
- 7. Updates to Area of Interest #6: Burn and Blast Medical Countermeasures
  - Updated TRL Requirement
- 8. Updates to Area of Interest #7: Diagnostics
  - Updated AOI 7.1.3 Biothreat Agent Diagnostics: Filovirus Point-of-Care and Remote Settings
  - Updated AOI 7.3.1 Influenza Home-Use Testing (for OTC or Prescription At-home)
  - Updated AOI 7.3.3 Point-of-Care Multiplex Assay for Detection of Influenza Virus
- 9. Updates to Area of Interest #9: IEID Therapeutics
  - Added new Area of Interest 9.4 COVID-19 Monoclonal Antibody Therapeutics for Treatment
  - Updated Additional Assessment Factors for the Specific Topic AOIs
- 10. Suspend AOI #11: COVID-19 Immune Assay(s) Development and Implementation