

*Insert Facility/Institute Logo Here*

**STANDARD OPERATING PROCEDURE (SOP) *TEMPLATE***

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| Facility: | |
| SOP Title: *Valuable Biological Inventory Management SOP* | |
| Document Number: *1-04-002* | Version Number: *00* |
| Process Leader: | Effective Date: *MM-DD-YYYY* |
| Other documents cross-referenced in this SOP (i.e., manuals, SOPs, forms, records):   * Biorisk Management Manual: Chapter V, Biorisk Assessment; Chapter XV, Material Control and Accountability; Chapter XIX, Waste Handling and Disposal; Chapter XXI, Emergency and Incident Response, Reporting and Investigation; Chapter XXII, Biorisk Management System Assessment and Improvement (*4-00-001*) * Transportation and Shipping SOP (*4-02-006*) * Waste Handling and Disposal SOP (*4-02-008*) | |

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| Revision Number | Sections Changed | Description of Change | Date | Approved By |
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INSTRUCTIONS: The Biorisk Management Manual and supporting Standard Operating Procedure (SOP) templates provide a general overview of common considerations and information that should be addressed within a biorisk management system and program. These templates are not exhaustive and facilities must customize each document to ensure it is locally applicable and relevant.

* **Black text** can be considered generic text which may be appropriate for inclusion in a facility’s biorisk management manual and SOPs.
* ***Red text*** should be considered guidance or examples and must be reviewed and replaced with facility-specific information.

1. Purpose

The purpose of this document is to establish the procedures for accountability and inventory management of valuable biological materials (VBM) in *[Insert Facility Name]* to ensure proper recordkeeping of VBM receipt, storage, use, transfer and disposal.

1. Scope

This document applies to all facility personnel and vsistors who have access to VBM and any associated information and inventory management systems within *[Insert Facility Name]*.

1. Responsibilities

* **Process Leader** ensures that:
  + This SOP is established and implemented effectively to include periodic inventory management system audits and reconciliation
  + Authorized users are trained on this procedure and competent prior to independent work involving VBM inventory management
* **Facility personnel**:
  + Follow the procedures outlined in this SOP
  + Report any problems to the Process Leader
* **Scientific *Manager/Director****:*
  + Defines VBM to be included in the inventory management system based on risk assessment and applicable local, national, and international guidelines, standards, and regulations
  + Determines material accountability processes that oversee and ensure safe and secure movement of VBM within the facility
  + Determines which personnel are authorized for access to VBM and any associated information and inventory management systems

1. Preparation
   1. Materials

* VBM *(as defined by the Scientific* *Manager/Director such as collections and reference strains, pathogens and toxins, vaccines and other pharmaceutical products, animals, genetically modified organisms, radiolabelled biological compounds, hazardous chemicals, and critical biological equipment, supplies and reagents)*
  1. Equipment
* *Computer(s) (if using electronic/spreadsheet/database inventory system)*
  1. Records and Forms
* Inventory Management System *(i.e., paper-based/notebook, electronic/spreadsheet/database)* and associated form(s) for VBM receipt, storage, use, transfer and disposal (refer to Attachment B, Valuable Biological Material Inventory Log Template)

1. Procedure *(refer to Attachment A, Valuable Biological Material Inventory Management SOP Template Flow Chart)*
   1. Identify VBM
      1. *Describe steps to determine the types of materials to be included in the VBM inventory management system using questions and comments from flow chart step 1*
   2. Identify Inventory Management System
      1. *Describe steps to determine the type of inventory management system and level of information to be included in the VBM inventory management system using questions and comments from flow chart step 2*
   3. Receipt
      1. *Describe steps to determine when and how VBM receipt is recorded using questions and comments from flow chart step 3*
   4. Storage
      1. *Describe steps to determine when and how VBM storage is recorded using questions and comments from flow chart step 4*
   5. Use
      1. *Describe steps to determine when and how VBM use is recorded using questions and comments from flow chart step 5*
   6. Transfer
      1. *Describe steps to determine when and how VBM transfers are recorded using questions and comments from flow chart step 6*
   7. Disposal
      1. *Describe steps to determine when and how VBM disposal is recorded using questions and comments from flow chart step 7*
   8. System Validation and Inventory Reconciliation
      1. *Describe steps to determine when and how the VBM inventory management system is validated to include the inventory reconciliation processes using questions and comments from flow chart step 8*
2. References
   1. Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, <https://www.cdc.gov/labs/BMBL.html>
   2. ISO 35001:2019, Biorisk management for laboratories and other related organisations. <https://www.iso.org/standard/71293.html>
   3. World Health Organisation (WHO), Biorisk Management: Laboratory Biosecurity Guidance, September 2006, <http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf>
3. Attachments
   1. Valuable Biological Material Inventory Management SOP Template Flow Chart
   2. Valuable Biological Material Inventory Log Template



* *How is the system validated (e.g., frequency of auditing and* *inventory reconciliation)?*
* *Who is notified of discrepancies?*
* *How are discrepancies resolved?*
* *Describe the process for investigating/evaluating lessons learned/ implementing corrective actions. Track status in Incident Response Form and Log*
* *Refer to BRM Manual: Chapter XXI, Emergency and Incident Response, Reporting and Investigation; Chapter XXII, Biorisk Management System Assessment and Improvement*