



PI Self-Assessment Checklist for IBC Protocols

PURPOSE

This checklist is designed to help Principal Investigators (PIs):

- Review current activities and documentation under the IBC-approved protocol.
- Prepare for the PAVE evaluation process.
- Identify records applicable to the digital review.

INSTRUCTIONS

Complete the Protocol Information section using the current IBC-approved protocol and the project's current status.

Because each protocol is different, not every item will apply. For each item, select **Yes**, **No**, **Not Applicable**, or **Unsure**. PAVE will review only the activities, materials, procedures, and records applicable to the approved protocol.

Upload only the records applicable to activities conducted under the approved protocol. If no additional records are available or applicable, upload only the completed self-assessment.

Before submitting the form, please ensure that the PI Acknowledgement is completed and signed.

I. PROTOCOL INFORMATION

Principal Investigator:

IBC Protocol Number:

Study Title:

Biosafety Level: BSL-1 ☐
BSL-2 ☐

Linked Institutional Approval, if applicable: ☐ IACUC
☐ IRB

Funding Source: ☐ Federal
☐ Non-federal

Current Study Status:

- | | |
|--|--|
| ☐ Approved, but activities have not started | ☐ Data analysis or dissemination is ongoing |
| ☐ Approved activities are ongoing | ☐ All protocol activities are complete |
| ☐ Laboratory activities have ended, but records or materials are still maintained | ☐ Other: |

II. IACUC APPROVAL AND STUDY ACTIVITIES

- | | Yes | No | N/A | Unsure |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| • IBC approval was received before protocol activities began. | ☐ | ☐ | ☐ | ☐ |
| • Current activities, materials, agents, and procedures remain aligned with the approved protocol. | ☐ | ☐ | ☐ | ☐ |
| • Changes requiring IBC review were approved before implementation. | ☐ | ☐ | ☐ | ☐ |
| • Activities are conducted only in the locations approved by the IBC. | ☐ | ☐ | ☐ | ☐ |

III. STUDY TEAM AND TRAINING

- | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| • All personnel performing protocol activities are listed on the approved protocol. | ☐ | ☐ | ☐ | ☐ |
| • Personnel complete required training before performing animal activities. | ☐ | ☐ | ☐ | ☐ |

IV. MATERIALS AND STUDY RECORDS

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| • Inventories or records of regulated materials are current when applicable. | ☐ | ☐ | ☐ | ☐ |
| • Procedure, transfer, receipt, use, or disposition records are maintained when required. | ☐ | ☐ | ☐ | ☐ |
| • Records of incidents, deviations, exposures, or corrective actions are maintained when applicable. | ☐ | ☐ | ☐ | ☐ |

V. DIGITAL UPLOAD DOCUMENTATION

Please **identify and upload** only the study records that apply to the activities conducted under the approved protocol. These may include:

- | | |
|---|--|
| ☐ Inventory of biological agents, toxins, or regulated materials | ☐ IBC-approved protocol-specific procedures or SOPs |
| ☐ Receipt, transfer, use, or disposition records | ☐ No additional records are available or applicable |
| ☐ Protocol-specific procedure or activity records | ☐ Other: _____ |
| ☐ Incident, exposure, or deviation documentation | |

VI. PI ACKNOWLEDGEMENT

Principal Investigator Signature: _____