



PI Self-Assessment Checklist for IRB Protocols

PURPOSE

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

- **Review** current study activities and documentation.
- **Prepare** for the evaluation process.
- **Identify** documents applicable to the PAVE digital review.

INSTRUCTIONS

Please complete the **Protocol Information** section using your current IRB-approved protocol and the study's current status.

Because each study is different, not every item or section will apply. For each applicable item, select **Yes, No, Not Applicable, or Unsure**. PAVE will use your responses to guide the evaluation and will review the study only in relation to its IRB-approved activities, procedures, and applicable requirements.

Complete the **Clinical Research and Investigational Products** section only if it applies to your study. You may leave this section blank if your protocol does not involve these activities.

In the **Digital Upload Documentation** section, identify and upload only the study records that apply to the activities conducted under the approved protocol. If no study records are available or applicable, upload only the completed self-assessment.

PAVE will be happy to discuss any questions or areas requiring clarification during the exit interview and provide guidance and support as needed.

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

I. PROTOCOL INFORMATION

Principal Investigator:

IRB Protocol Number:

Study Title:

IRB Review Category: ☐ Exempt
☐ Expedited
☐ Full Board
☐ Unsure

Approved Enrollment Goal:
 Number Enrolled:
 Number Withdrawn:

Funding Source: ☐ Federal
☐ Non-federal

Current Study Status:

- | | |
|--|---|
| ☐ Approved, but activities have not started | ☐ Data analysis or dissemination of results is ongoing |
| ☐ Recruitment, enrollment, or participant interaction is ongoing | ☐ All study activities are complete |
| ☐ Enrollment has ended, but other study activities continue | ☐ Other: |
| ☐ The study does not involve participant enrollment and is limited to data analysis | |

II. IRB APPROVAL AND STUDY ACTIVITIES

- | | Yes | No | N/A | Unsure |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| • IRB approval was received before study activities began. | ☐ | ☐ | ☐ | ☐ |
| • All current study activities remain aligned with the IRB-approved protocol. | ☐ | ☐ | ☐ | ☐ |
| • All Changes requiring IRB review were approved before implementation. | ☐ | ☐ | ☐ | ☐ |

III. STUDY TEAM AND TRAINING

- | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| • All study personnel are listed on the approved protocol. | ☐ | ☐ | ☐ | ☐ |
| • All study personnel have their CITI training current and complete before performing study activities. | ☐ | ☐ | ☐ | ☐ |

IV. RECRUITMENT, ENROLLMENT, AND CONSENT

- | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| • Recruitment methods and materials remain consistent with the approved protocol. | ☐ | ☐ | ☐ | ☐ |
|---|--------------------------|--------------------------|--------------------------|--------------------------|

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The University of Texas at El Paso | Research & Innovation

- | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| • Enrollment remains within the IRB-approved number. | ☐ | ☐ | ☐ | ☐ |
| • Screening, enrollment, and withdrawal records are maintained when applicable. | ☐ | ☐ | ☐ | ☐ |
| • The approved consent process is followed before study procedures begin. | ☐ | ☐ | ☐ | ☐ |
| • The current approved written, electronic, or verbal consent materials are used. | ☐ | ☐ | ☐ | ☐ |
| • Written, electronic, or verbal consent is documented as approved. | ☐ | ☐ | ☐ | ☐ |
| • Assent and parental permission are obtained when applicable. | ☐ | ☐ | ☐ | ☐ |
| • Approved translated materials are used when applicable. | ☐ | ☐ | ☐ | ☐ |

V. DATA, PRIVACY, AND RECORDKEEPING

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| • Data is collected using approved methods and instruments. | ☐ | ☐ | ☐ | ☐ |
| • Physical and electronic records are stored securely. | ☐ | ☐ | ☐ | ☐ |
| • Access to identifiable information is limited to authorized personnel. | ☐ | ☐ | ☐ | ☐ |
| • Identifiers are coded, separated, or removed as approved. | ☐ | ☐ | ☐ | ☐ |
| • Audio, video, photographs, or recordings are used and maintained as approved. | ☐ | ☐ | ☐ | ☐ |
| • Data sharing, retention, and destruction remain consistent with the approved protocol. | ☐ | ☐ | ☐ | ☐ |
| • Compensation records are maintained when participants are compensated. | ☐ | ☐ | ☐ | ☐ |

VI. CLINICAL RESEARCH AND INVESTIGATIONAL PRODUCTS

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| • Clinical or health-related procedures are conducted as approved. | ☐ | ☐ | ☐ | ☐ |
| • Source documentation and Case Report Forms are maintained when applicable. | ☐ | ☐ | ☐ | ☐ |
| • Participant safety monitoring is conducted as approved. | ☐ | ☐ | ☐ | ☐ |
| • Good Clinical Practice training is current when required. | ☐ | ☐ | ☐ | ☐ |
| • ClinicalTrials.gov registration and updates are current when required. | ☐ | ☐ | ☐ | ☐ |
| • IND, IDE, or exemption documentation is current when applicable. | ☐ | ☐ | ☐ | ☐ |

VII. DIGITAL UPLOAD DOCUMENTATION

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

- | | |
|--|--|
| ☐ Signed written consent forms and/or FERPA forms | ☐ Completed data-collection instruments or study records |
| ☐ Electronic consent records | ☐ Documentation of data storage or security practices |
| ☐ Verbal consent script and documentation of verbal consent | ☐ Protocol deviation or reportable-event documentation |
| ☐ Signed assent or parental permission forms | ☐ Clinical research or investigational product records |
| ☐ Screening, enrollment, or withdrawal records | ☐ No additional study records are available or applicable |
| ☐ Compensation records | ☐ Other: _____ |

VIII. PI ACKNOWLEDGEMENT

Principal Investigator Signature: _____