

Audit Preparation Checklist for Researchers

General Preparation

- ☐ Review the notification letter to understand scope, required documents, and timeline
- ☐ Organize all requested documents in a logical order
- ☐ Identify primary contact person(s) for the review
- ☐ Notify all research team members about the upcoming review
- ☐ Ensure all lab/office space is reasonably organized and accessible

Documentation Review

- ☐ Current approved protocol/project authorization (IRB, IACUC, IBC, RSC)
- ☐ All protocol amendments and continuing review documentation
- ☐ Informed consent forms (all versions used)
- ☐ Training records for all personnel (CITI modules, protocol-specific training, RCR training)
- ☐ Regulatory correspondence with IRB, IACUC, IBC, RSC, or funding agencies
- ☐ Conflict of interest disclosures and management plans
- ☐ Current and pending support documentation
- ☐ Data management plan or data security documentation
- ☐ Research security disclosures (if applicable)
- ☐ Export control screening records (if applicable)

Records and Source Documents

- ☐ Source documents demonstrating research procedures followed approved protocol
- ☐ Records of participant/animal interactions, observations, or measurements
- ☐ Material accountability and inventory records (for radioactive material, biological materials, etc.)
- ☐ Safety incident/adverse event reports and follow-up
- ☐ Deviation/protocol deviation reports
- ☐ Quality assurance or quality control documentation

Special Considerations

- ☐ If any significant findings or issues have been identified since last review, prepare documentation
- ☐ If a for-cause review, do not alter, delete, or create documentation before the review
- ☐ Identify any areas where you have questions or need clarification on compliance
- ☐ Ensure key personnel are available for interviews (if requested)