



University of Arizona Internal Audit Guide ORP Quality and Compliance Version 1 : 19 December 2025

Introduction and Purpose

The Office of Research and Partnerships (ORP) Quality and Compliance audit team serve as a resource to the University of Arizona (UA) research community by providing centralized internal auditing to support the adherence to the core principles of research best practices. Our mission is to take a collaborative approach with UA study teams by considering these audits as study wellness checks*.

Protocols are selected following a risk-based approach, random selection, and directed for-cause audit requests from compliance offices and leadership.

All research involving human subjects at the University of Arizona is subject to review and inspection at any time and may benefit from internal review. The purpose of an internal wellness check is to ensure:

- Human subject protection: The safety, welfare, and rights of human subjects are protected.
- Data integrity and study validity: Data are reliable, accurate, complete, and verified from source documentation
- Compliance with University of Arizona IRB approved protocol(s)/amendment(s); with ICH GCP; institutional policies and procedures; and applicable laws, federal regulations, and guidance.

Wellness checks promote continuous quality improvement opportunities by providing increased awareness and understanding of regulatory obligations; clinical trial support and serving as a resource to study teams; and constructive feedback.

*The term audit and wellness check are used interchangeably. Auditors will also be referenced as reviewers.

Required Documents

Please ensure the following is available for the ORP reviewer(s) during the Wellness Check:

Regulatory Binder	<ul style="list-style-type: none"> ✓ Approved protocol(s) (current, previous, and original) with signed protocol signature pages ✓ IRB approval letters and communications ✓ Study Delegation of Authority and training log(s) ✓ Site Standard Operating Procedures (SOPs) ✓ Signed FDA Form 1571/1572 (as applicable) ✓ Investigator Licensure and curricula vitae (CV) ✓ Study staff curricula vitae
Informed Consent/ HIPAA Authorization	<ul style="list-style-type: none"> ✓ IRB approved consent form(s) current, previous, and original ✓ HIPAA authorization document ✓ Informed Consent process documentation including:

	<ul style="list-style-type: none"> ○ Participant signature obtained prior to any study related activities ○ Date/time of consent review, persons present, and type of discussion (in person, phone, video) ○ Ample time provided to participant/LAR to review and ask questions ✓ Consent form available for review in subject chart ✓ Documentation of any discrepancies on consent form ✓ Documentation of premature discontinuation / withdrawal of consent (as applicable)
Subject Eligibility	<ul style="list-style-type: none"> ✓ Documentation of Inclusion / Exclusion criteria met ✓ Screening and Enrollment log(s) (as applicable)
Safety / Protocol Deviations	<ul style="list-style-type: none"> ✓ All AE/SAEs are documented and reported ✓ Protocol deviation documentation and notifications
Data Integrity	<ul style="list-style-type: none"> ✓ Source data corroborates with study data as reported in the case report forms / data collection tools ✓ Access to data capture system and case report forms ✓ Subject chart including study visit notes/ documentation, medical records, physician orders, lab result, test results, concomitant medication records (as applicable)
Pharmacy / Device Documentation (as applicable)	<ul style="list-style-type: none"> ✓ Investigation product / Device accountability log(s) ✓ Shipping receipts / packing slips ✓ Temperature log (s) ✓ IP policies and procedures

Audit/Wellness Check Conclusion and Follow-up

At the conclusion of the visit, the auditor will meet with the PI and key study staff for a close out meeting. The close-out meeting can be scheduled for another day if necessary. The auditor will answer any questions and will present the preliminary audit findings to the PI and study team. The auditor will provide recommendations and educational support on record retention and documentation, and other compliance related issues.

The auditor will complete a formal internal audit summary report and will provide a copy to the PI and study team within two (2) weeks of completion of the visit. The report will include a PI signature line for acknowledgment of receipt and review.

Please note that the auditor will promptly report observations that raise the level of potentially serious and/or continuing non-compliance and/or other events that involve risk to subjects or others to the IRB and appropriate regulatory committees.

Following the review of the final report, it is requested that the PI promptly email an electronically signed copy of the report to the auditor along with the response to any observations and action items noted on the report.

The signed copy of the report and the PI response will be forwarded to the IRB for review and assessment. The IRB will make their determination and will inform the investigator and study team if additional actions are required.