University Hospitals
Clinical Research Center

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AUDIT READINESS – A CULTURE OF COMPLIANCE

Research compliance reviews and audits are unavoidable when you are engaged in research. At UH, research compliance reviews by the Clinical Research Center (CRC) Research Compliance Team are an institutional mandate with focus on decreasing risk to the institution, and ensuring UH research participant safety.

We are here to support study compliance, and if there happens to be a research compliance finding, we will provide tools and guidance to help steer you back on the correct path.

WHAT IS A FINDING?

A "finding" is non-compliance with the conduct or oversight of research that fails to comply with one or more of the following:

- Federal Regulations
- The IRB approved protocol or investigational plan
- Policies - Institution, IRB, Sponsor, Funding agency
- Standard Operating Procedures (SOPs) - Institution or Department

Common FDA Findings Nationally

Investigator Deficiencies

- Failure to follow the investigational plan/agreement
- Inadequate communication with the IRB

IRB Deficiencies

- Inadequate written procedures

Sponsor/Monitor Deficiencies

- Inadequate monitoring

Bioequivalence Deficiencies

- Analytical Concerns–validation and/or stability

Good Laboratory Practice (GLP) Deficiencies

- Inadequate or no Standard Operating Procedures (SOPs)
- Inadequate archiving

Common UH Research Compliance Findings

Study Personnel

Regulatory Binder and Essential Documents

Informed Consent Process and Documentation

Eligibility Assessment

Data Collection and Good Documentation Practices

Adverse Events and Protocol Deviation Reporting and Documentation

MAINTAINING COMPLIANCE

After receiving IRB approval, researchers must take additional measures to maintain compliant study conduct and avoid findings and stipulations.

Here are a few ongoing responsibilities:

- Enrollment Numbers
  Know your enrollment numbers (i.e., total and for the year). Ensure the number of participants approved in the IRB form is meaningful for your protocol. Do not exceed your enrollment goal (i.e., over-enroll) without prior permission. Discrepancies are often found during Continuing Review when numbers do not align with those reported the previous year, or the number input exceeds the approved amount. Track your enrollment numbers with a screening and enrollment log.

- Personnel Tables, CREC Certification, and Research Credentialing
  Must be updated in real-time. If a person is added or removed from the study (e.g., if they are no longer with the team), then a modification should be submitted to the IRB. Personnel tables must to be updated to reflect an approved modification. The study team is responsible for monitoring expiring certifications and credentials.

- Modifications are not pro forma
  The approved protocol and answers prescribe study parameters. Any deviation from the approved protocol should be submitted, reviewed, and approved **BEFORE** that change is implemented. All changes require an accompanying rationale, even if it seems self-explanatory. Changes to documents should be disclosed in the description of the modification.

- Specimens and Discarded Tissues
  Ensure specimens are collected, transported, stored, and documented per protocol. This also includes temperature monitoring with provisions in place for potential sample storage failure.

- Data Storage, Sharing, and Access
  Data storage plans must be reviewed, approved, and meet UH IT Security standards. The approved storage plan must be followed and any changes or deviations from the approved plan must be submitted, reviewed, and approved by the IRB. IRB approval is only for a specific set of data. Collection of additional data will require IRB approval. Ensure adequate provisions are in place to protect and maintain the privacy and confidentiality of participant data - e. g. password protection and limited access.

- Informed Consent and Eligibility
  As applicable, the informed consent process must be documented via a checklist or narrative note. Ensure that documentation or verification of protocol specific inclusion & exclusion criteria is present, regardless if it is for participants (interventions & observations) or when accessing patient data (chart reviews, repositories, etc.)

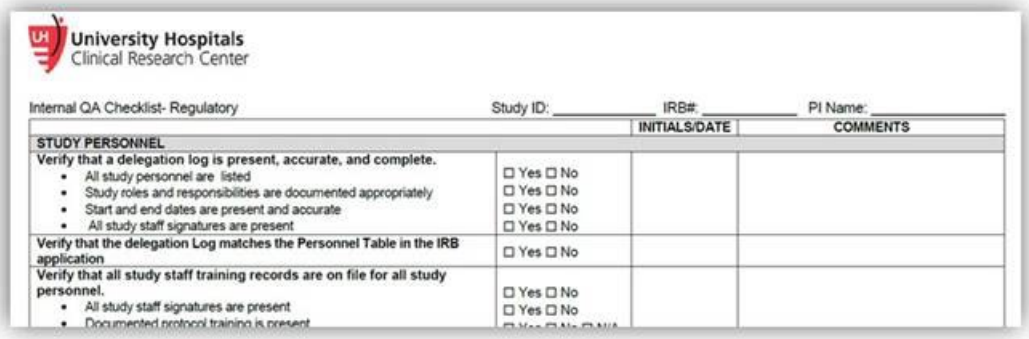
Review the Investigator Manual for IRB Submissions for guidance on additional responsibilities.

INTERNAL QA TOOLS

The CRC has developed two internal research quality assurance (QA) checklists to help keep you inspection ready and avoid common findings:

1. **Internal QA Checklist- Participant**
    - Covers Informed Consent and HIPAA Authorization, PHI, Safety Reporting, Drug/Device Accountability, Specimen processing and handling, Data Collection and Source Documentation, Financial Information

2. **Internal QA Checklist- Regulatory**
    - Covers Study Personnel, Regulatory Binder, Safety Reporting, Data Safety Monitoring Board (DSMB), Monitoring, ClinicalTrials.gov, Research Financials , Protocol, Screening and Enrollment, Drug/Device Accountability



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Internal QA Checklist- Regulatory Study ID: _____ IRB#: _____ PI Name: _____

		INITIALS/DATE	COMMENTS
STUDY PERSONNEL			
Verify that a delegation log is present, accurate, and complete. • All study personnel are listed • Study roles and responsibilities are documented appropriately • Start and end dates are present and accurate • All study staff signatures are present	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No		
Verify that the delegation Log matches the Personnel Table in the IRB application	☐ Yes ☐ No		
Verify that all study staff training records are on file for all study personnel. • All study staff signatures are present • Documented protocol training is present	☐ Yes ☐ No ☐ Yes ☐ No		

Both QA checklists are available for immediate use and can be found in the **Compliance Tools** section of the UH Research Toolbox along with other helpful materials.

For prospective or retrospective chart reviews, biorepositories, discarded tissue and blood sample banking, exempt research, questionnaire studies, and behavioral research, not all information contained within the internal QA tools are applicable. Mark N/A on the worksheets accordingly when reviewed.

We recommend using these tools throughout your research journey and, specifically, at time points that make sense for the type of research you are doing. Consider the following:

- Prior to compliance reviews (both internal and external)
- With major changes in study design
- At milestones throughout the study
- Random intervals
- At study closure

AVOIDING NON-COMPLIANCE FINDINGS

Please consider reviewing the Research Education session **The Basics: Module 9 – Avoiding Non-Compliance Findings** in UH GPS.

Presented by Carrie O'Neill, this session will review the most common non-compliance findings and provide practical tips and tools to help research teams prevent them.

Register via UH GPS:

- Employees
- Research Credentialed & Self-Registration Users

Remember: Research compliance is an ongoing process and we are here to help. We can clarify issues and recommend remedies, but it is up to you to take the necessary actions throughout the life of your study to maintain compliance. By building a culture of compliance within your study team and having an audit-ready mindset, you'll be prepared if and when an external authority comes knocking.

For additional guidance:

UH Research Compliance: UHResearchCompliance@UHhospitals.org
UH IRB Administration Office: UHIRB@UHhospitals.org, 216-844-1529
UH Research Integration & Education: ClinicalResearch@UHhospitals.org

www.UHhospitals.org/Clinical-Research