

Building and Sustaining Research Compliance Programs

Practical Design. Aligned Governance. Ongoing Support.

The Opportunity

Clinical research programs continue to grow in complexity, requiring coordination across compliance, research operations, legal, and finance. Effective research compliance programs move beyond policies alone and are designed to support consistent, scalable, sustainable, and real-time decision-making across research operations.

PYA helps clients design research compliance programs that

- Include compliance in daily research operations
- Align stakeholders across functions
- Support consistent, defensible decision-making
- Scale with program growth and regulatory expectations

Elements of PYA's Research Compliance Program Design & Build



Governance & Structure

Oversight models, committees, and reporting lines



Policies & Procedures

Research-specific policies, operational standard operating procedures, and supporting standards to guide consistent execution



Risk Assessment & Work Planning

Identification of risks and development of compliance work plans



Roles & Accountability

Clear delineation across compliance, research, legal, and finance



Program Infrastructure

Escalation, issue tracking, and reporting frameworks

Who We Serve

ACADEMIC MEDICAL CENTERS

| HEALTH SYSTEMS

| PRIVATE MEDICAL PRACTICES

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How PYA Helps

We partner with healthcare organizations to design, build, and support research compliance programs that are

- Strategic and tailored
- Operationally integrated
- Scalable and flexible
- Collaborative and practical

What Makes Our Approach Different

We combine strategy, operations, and compliance expertise to deliver solutions that work in real-world research environments. Our approach focuses on translating regulatory expectations into practical, repeatable processes that align with existing research and financial workflows and can be sustained over time.

- Practical, implementable program design
- Alignment with research and financial workflows
- Flexible support models
- Clear, usable frameworks organizations can sustain

How Our Advisory Services Support You

Our advisory and ongoing support include key services:

- Comprehensive risk assessments and audit and monitoring program support
- Ad hoc advisory provided through PYA's Compliance Overwatch Program
- Training for investigators, study teams, institutional stakeholders, and finance personnel
- Regulatory and sponsor audit readiness, including evaluation of program controls, documentation, and response processes

The Benefits to You

- ✓ Establish a clear, defensible compliance framework
- ✓ Reduce regulatory and financial risk
- ✓ Strengthen cross-functional coordination
- ✓ Improve audit readiness
- ✓ Support sustainable research program growth

Build a research compliance program that works in practice, not just on paper.

Learn more about PYA's approach to compliance at pyapc.com/research-compliance.