Regulation and Compliance in Family Medicine Research

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1. Introduction

Research in family medicine is essential for advancing evidence-based primary care. However, regulatory compliance is critical to ensure ethical integrity, institutional accountability, and the protection of human subjects. Department chairs play a key leadership role in establishing a research culture that prioritizes regulatory literacy and institutional compliance.

This white paper provides a comprehensive guide to understanding and managing regulatory processes, institutional expectations, and grant management responsibilities for family medicine research programs.

2. Foundations of Regulatory Compliance

All personnel involved in research — including faculty, residents, students, and staff — must complete required institutional trainings such as Human Subjects and Animal Research Training. Chairs should ensure that faculty and trainees are aware of these requirements and maintain compliance through consistent monitoring and communication.

3. Institutional Review Board (IRB)

Department chairs should foster strong, collaborative relationships with their IRB. This includes identifying liaisons, understanding submission processes, and providing faculty access to IRB training. Key considerations include determining exempt protocols (including quality improvement), consent requirements, and data safety monitoring needs. Having examples of successful IRB applications as well as a list of pitfalls to avoid can help prevent mistakes on submissions. Knowing IRB timelines, pre-review processes, and trained coordinators can streamline IRB efficiency.

4. Clinical Trials Office (CTO)

The CTO supports clinical research activities. Chairs should identify liaisons and ensure faculty understand available supports, including coordinator pools, budgeting guidance, and contract liaisons. This ensures compliance with institutional and sponsor regulations. Ask if there is a cost associated with CTO services.

5. Office of Sponsored Research (OSR)

The OSR oversees pre-award and post-award processes. Chairs should ensure faculty understand OSR organization, proposal routing, budget verification, and the distinction

between pre- and post-award functions. Coordination with development offices for foundation funding is also important.

6. Institutional Requirements

Departments must clarify who recruits participants and who controls access to clinical data. Data security and compliance with HIPAA and institutional policies are paramount. Chairs must ensure supervision of trainees and coordinators and establish advocacy pathways for resolving issues.

7. Grants Management

Each grant carries administrative responsibilities. Chairs should ensure faculty understand funder requirements, reporting obligations, and PI responsibilities. Awareness of funding limitations, cost caps, and institutional financial policies is essential for compliance and sustainability.

8. Summary and Recommendations

Chairs should learn and teach compliance, build relationships with regulatory offices, promote required training, establish departmental pre-review systems, and support administrative infrastructure. A robust compliance framework ensures ethical, credible, and sustainable research in family medicine.