Setting Up, Managing, and Maintaining a ClinicalTrials.gov Account: Insights from Institutions

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Session Overview

Objective:

To provide an in-depth look at how institutions manage ClinicalTrials.gov compliance and actionable insights to optimize compliance at your institution.

Core Topics:

- The importance of ClinicalTrials.gov registration
- Institutional strategies
- Key compliance challenges and solutions
- How IRB processes align with ClinicalTrials.gov requirements
- Best practices for results reporting and policy enforcement

Understanding ClinicalTrials.gov

ClinicalTrials.gov is a database managed by the NIH to ensure transparency in clinical research.

Key functions:

- Provides public access to clinical trial information
- Helps researchers comply with FDA, NIH, and institutional policies
- Supports transparency, credibility, and funding compliance
- Registration and results reporting are mandatory for applicable trials to maintain research integrity.

Institutional Strategies

- **Institution A**
- Has a structured process for ClinicalTrials.gov compliance:
- Uses Study Status Activation Page (SASP) to track compliance
- Ensures registration before study initiation
- Conducts internal quality control (QC) reviews for accuracy
- Proactively notifies researchers about updates and reporting deadlines

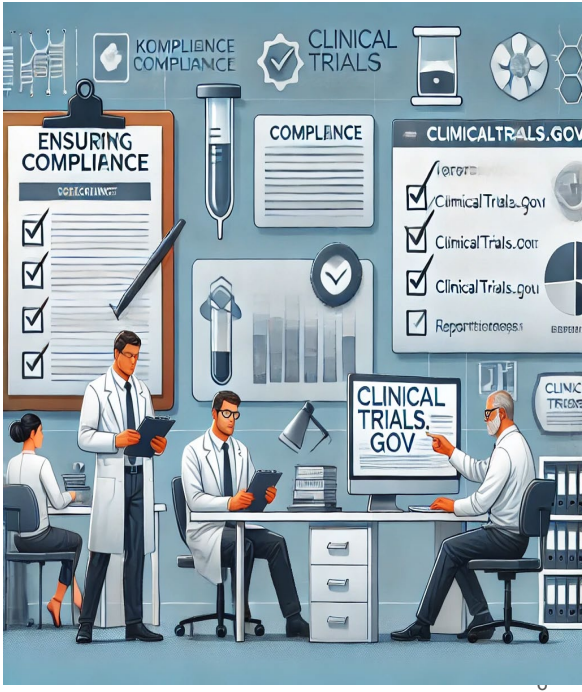
- **Institution B**
- Follows a PI-led approach with strong administrative support
- Investigators determine registration requirements
- Centralized system assists PIs in completing ClinicalTrials.gov registration
- Offers targeted training and real-time administrative support
- IRB plays a supportive role in ensuring compliance with ClinicalTrials.gov policies

Key Compliance Challenges in ClinicalTrials.gov

- Understanding regulatory terminology and its impact on compliance
- Meeting tight reporting deadlines and maintaining accurate records
- Ensuring data consistency across IRB, ClinicalTrials.gov, and grants
- Aligning IRB approvals with ClinicalTrials.gov study records to prevent discrepancies

Strategies for Ensuring Compliance

- Develop clear **internal policies** for researchers and administrators
- Provide **structured training** and ongoing support to study teams
- Implement **internal QC reviews** before submission to identify issues
- Use **escalation policies** and **internal deadlines** to prevent noncompliance

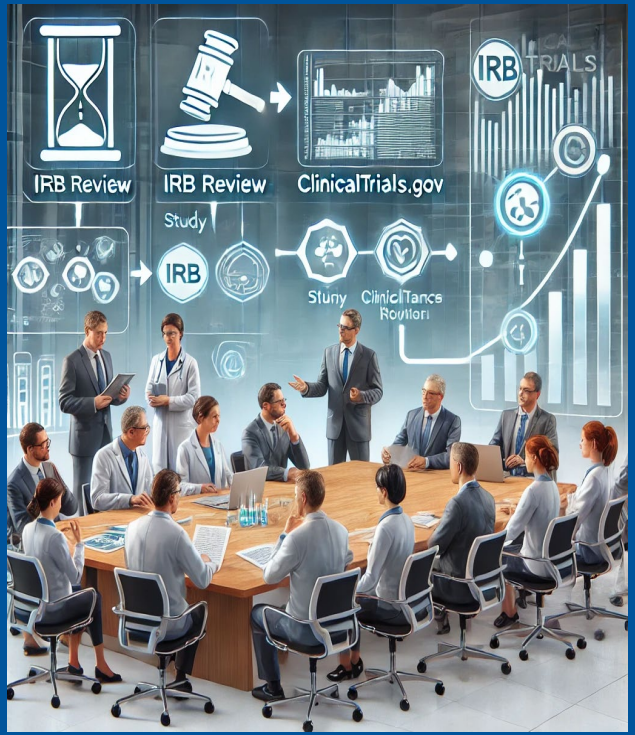


Results Reporting and Escalation Policies: a Critical Aspect of Compliance

- **Primary completion** dates determine reporting deadlines
- Internal deadlines ensure compliance ahead of Federal requirements
- Escalation measures are used to ensure researchers meet reporting obligations
- Statistical review support is provided to help teams meet Federal reporting criteria

Integrating IRB Processes with ClinicalTrials.gov

- Standardize processes for study protocol approval and registration
- Conduct routine cross-checks between IRB and ClinicalTrials.gov record
- Use IRB insights to support compliance tracking and researcher education
- Establish clear communication channels between IRB and research teams



Lessons Learned and Best Practices from Institutions A & B

- **Early integration** of compliance measures reduces registration delays
- **Training and direct support** improve Principal Investigator adherence
- **Internal QC reviews** ensure regulatory compliance and data integrity
- Escalation policies prevent **missed reporting deadlines** and funding risks

Conclusion & Final Thoughts

- Effective **collaboration** between PIs, administrators, and IRBs is essential
- Institutions must **balance compliance** with researcher burden
- **Continuous refinement** of processes improves efficiency and transparency
- Engage in **ongoing dialogue** to refine institutional policies

Questions and Discussion

~Thank you for your attention!

~Please feel free to ask questions, share insights, or discuss institutional challenges.

~ "Compliance is not about checking boxes;
it's about building trust in research, ensuring integrity,
and advancing discoveries that improve lives." ~

Peace, Renewal, and Clarity