

Research Compliance Auditing

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Overview

- **Overview of USF IRB**
- **History of USF Human Subject Protections Program**
- **USF Auditing Program**
- **Recommendations for a Successful Program**
- **Pearls for Developing a Robust, Credible Audit Program**

Human Subject Protections Program

- **Average Active Protocols (n=1500)**
 - **Biomedical Studies (n>800)**
- **Weekly Biomedical IRB Meetings**
- **IRB Professional Support (20 FTEs)**
 - **Assistant Directors-IRB and Quality Assurance (n=2)**
 - **Coordinators-Biosafety, IRB, HIPAA, and Education (n=4)**
 - **Senior Grant Specialists (n=8)**
 - **Grant Assistants (n=2)**
 - **Program Assistants (n=4)**
- **Budget \cong \$1,300,000**

History of USF Audit Program

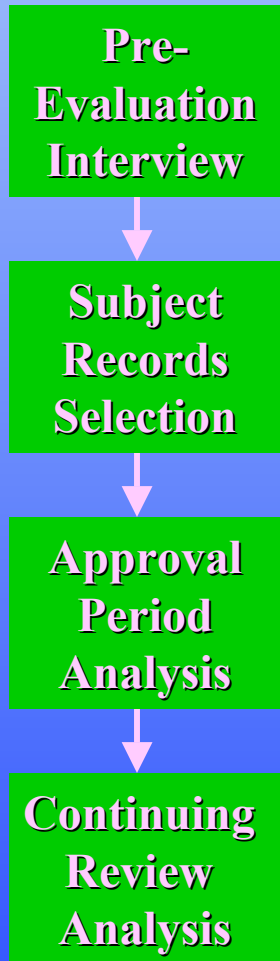
- Established in March 2002 with 1 FTE (currently 2 FTEs)
- Completed Audits to Date (n=9)
- Common Deficiencies/Findings
 - Informed Consent (IC) Documentation
 - Missing pages, signatures, dates
 - Subject consented with wrong version
 - Subject Records Organization
 - No documentation to demonstrate adherence to IRB-approved protocol
 - Research Records Organization

USF Audit Program Plans for Next year

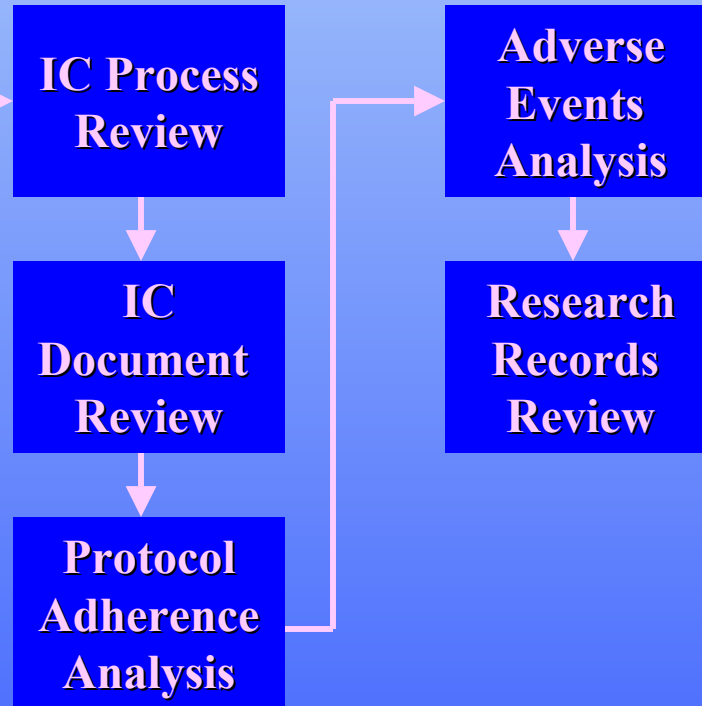
- **Increase Number Audits Completed Annually**
 - **For-Cause (average 4/year)**
 - **Randomly-Selected (4/year)**

USF Audit Process Summary

Pre-Evaluation



Evaluation

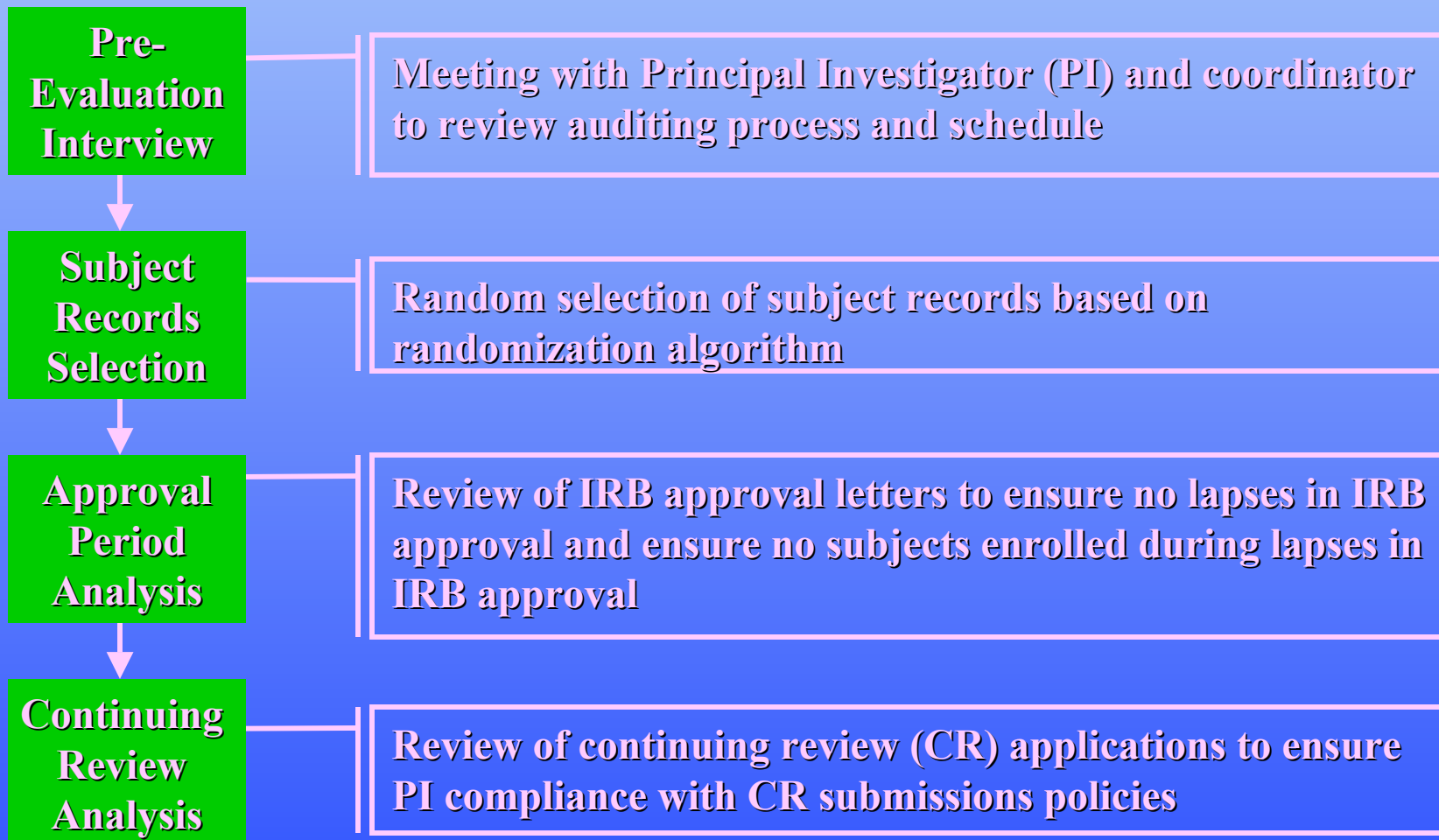


Post-Evaluation



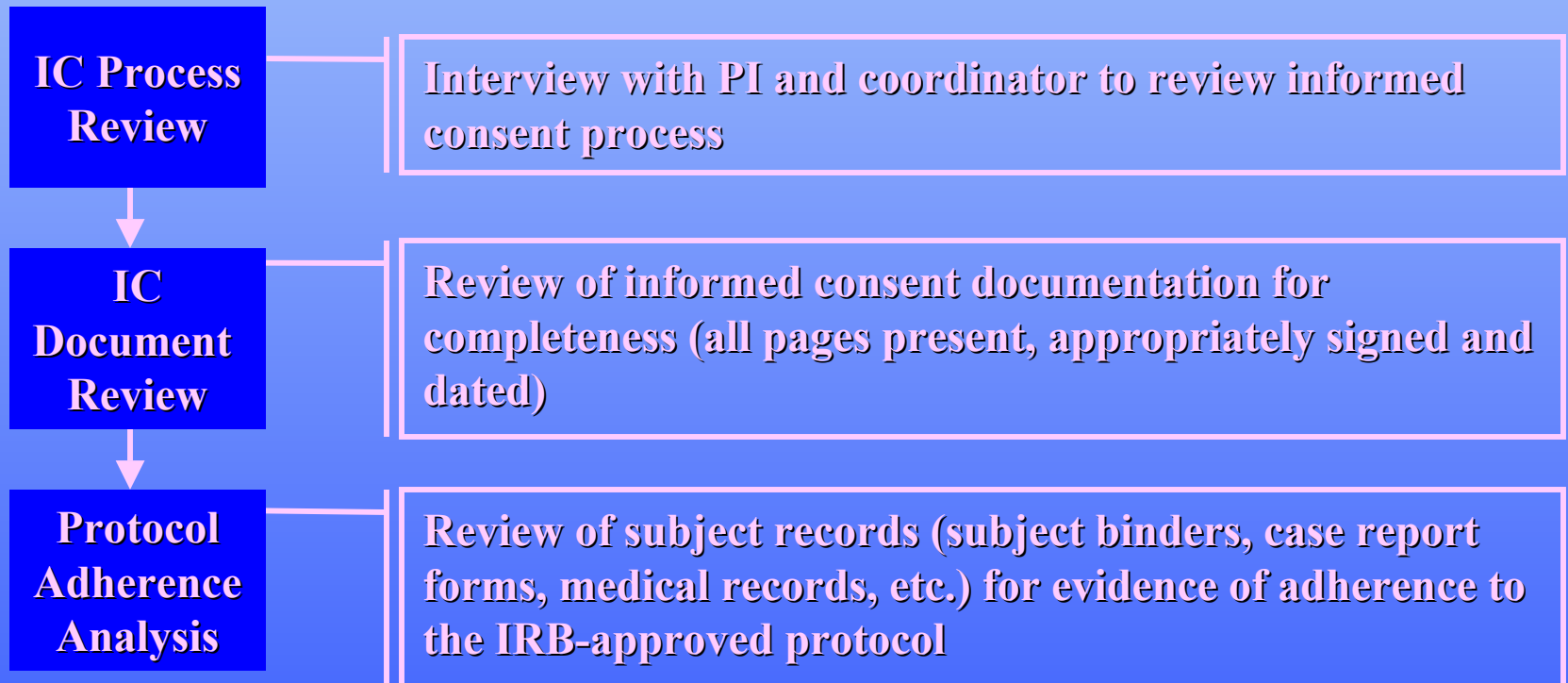
Pre-Evaluation

Interviews and IRB File Review



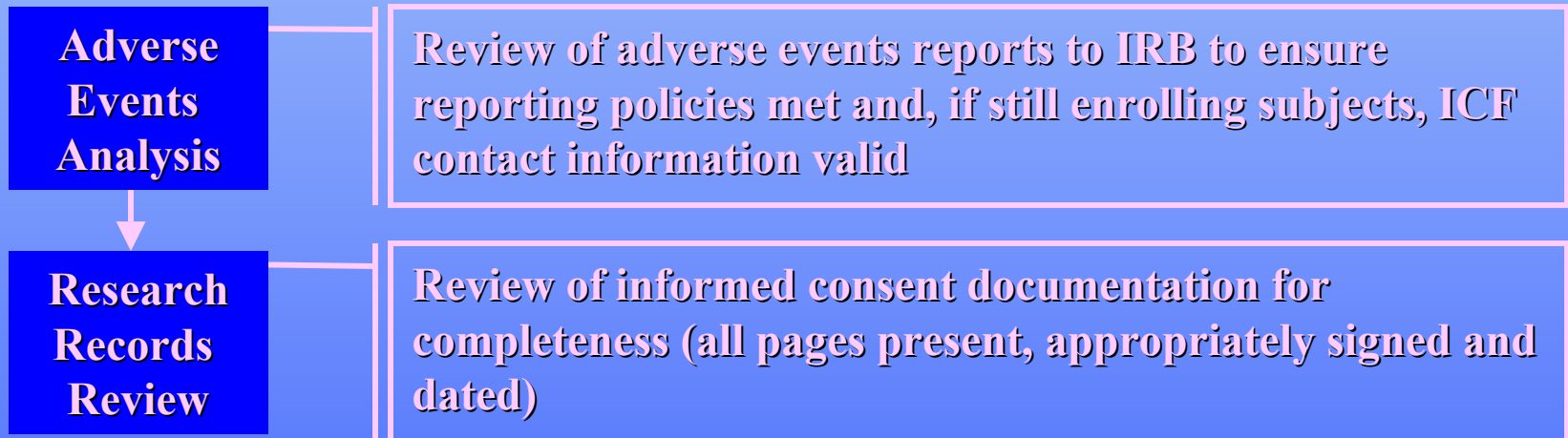
Evaluation

On-Site Records Review



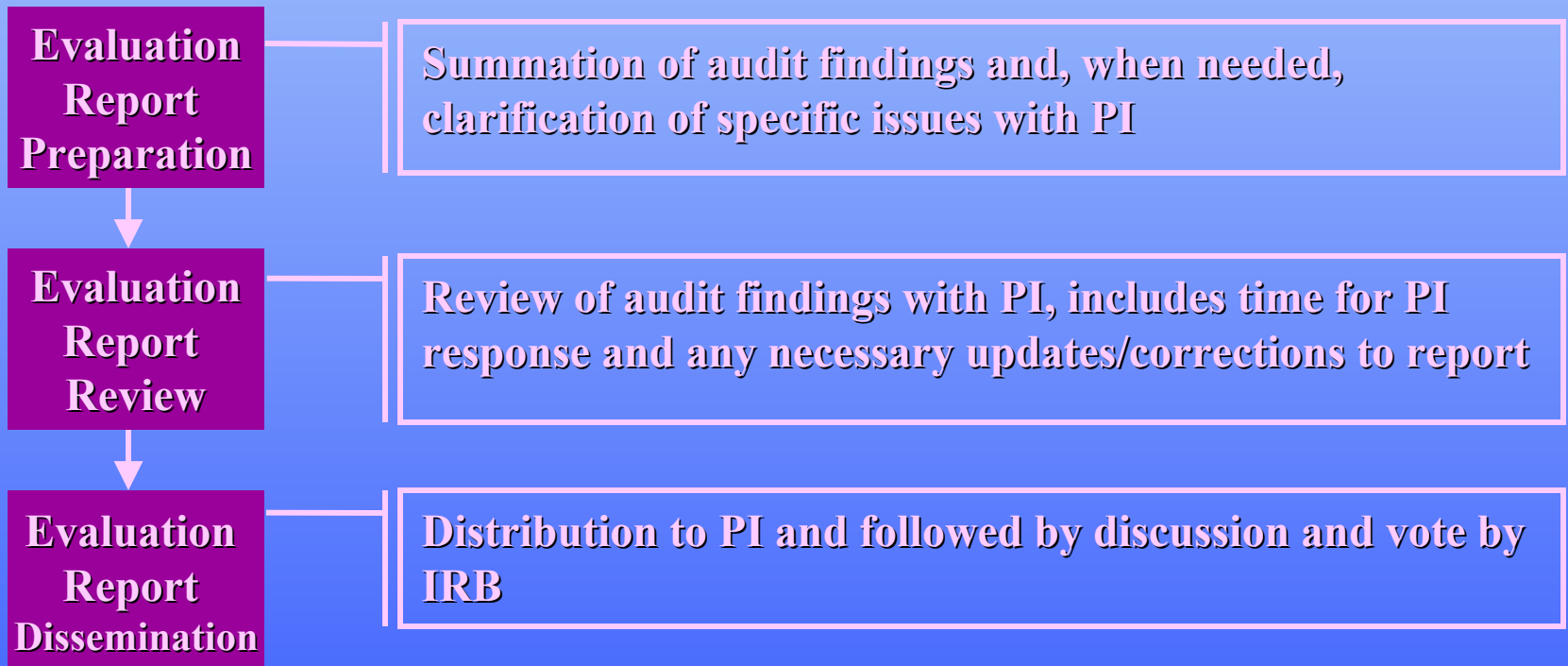
Evaluation

On-Site Records Review (cont'd)



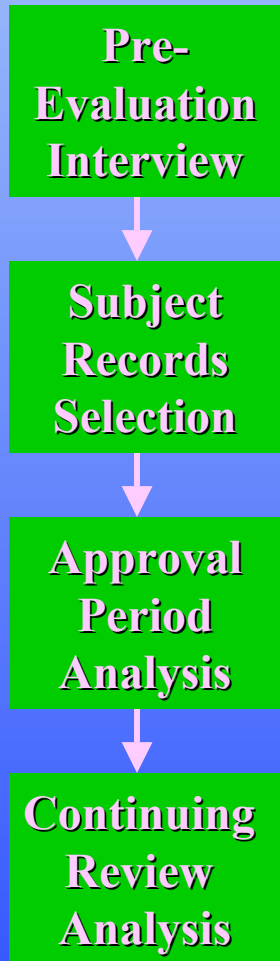
Post-Evaluation

Report Preparation and Dissemination

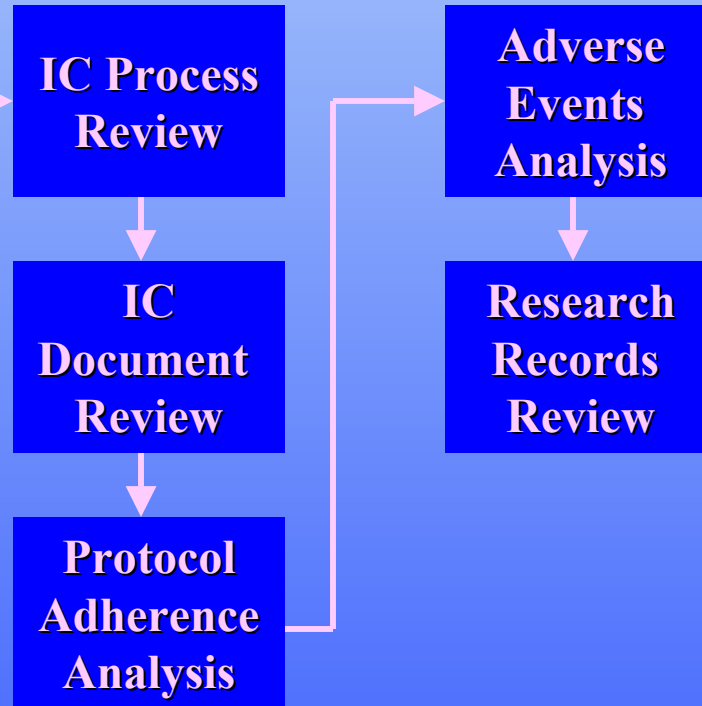


USF Audit Process Summary

Pre-Evaluation



Evaluation



Post-Evaluation



Recommendations for a Successful Program

- **Audit Program Implementation and Management**
 - **Clear Communication with Stakeholders**
 - **Documentation requirements**
 - **Audit process/timetable**
 - **Process Objectivity**
- **Investigators**
 - **Complete Records for Each Enrolled Subject**
 - **Organize Records (Chronological by Study Number)**
 - **Open Communication with Auditors to Ensure Understanding of Record-Keeping Expectations**

Pearls

- **Effective communication with stakeholders critical: PI, IRB members, University officials, and, when applicable, Affiliate Institutions**
- **Balancing collegiality with accountability**

Summary

- **Elements for Successful Program Reviewed**
- **Emphasis on Partnership Among Investigators, Coordinators, IRB Staff, and IRB Chair**
- **Need for Dedicated Individuals to Address Audit Volume (For-Cause and Randomly-Selected)**

Contacts



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